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ECBC-TR-526

EVALUATION OF THE STERIS SENSITIVE EQUIPMENT DECONTAMINATION (SED) APPARATUS ON A 463L PALLET

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14. ABSTRACT:
The STERIS Vaporous Hydrogen Peroxide (VHP®) technology has been used for more than a decade to sterilize pharmaceutical processing equipment and clean rooms. Through a joint partnership, the U.S. Army Edgewood Chemical and Biological Center (ECBC) and STERIS Corporation, Inc., subsidiary of Strategic Technology Enterprises (STE), began the process to co-develop a modified VHP (mVHP) capable of biological and chemical decontamination. Significant improvements have been made through a series of laboratory, chamber-scale, and large-scale efforts. The primary objective of this test was to determine the mVHP system ability to decontaminate representative articles of sensitive equipment and operationally relevant materials for biological-warfare agent surrogate contamination. A replica of the SED prototype decontamination chamber was constructed for use under engineering controls for live chemical agent evaluation. The biological-efficacy coupon and equipment tests were to determine the decontamination efficacy. The decontamination efficacy was compared to the KPPs stated in the ORD for JSSED. The secondary objective of this testing was to evaluate the impact of fumigant on the operability of the representative sensitive equipment. The tests were performed between October 2005 and March 2006 in a space provided by the 20th Support Command at ECBC.

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G. stearothermophilus	CARC	Silicone
Sensitive equipment	Glass	

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EXECUTIVE SUMMARY

The STERIS Vaporous Hydrogen Peroxide (VHP®) technology has been used for more than a decade to sterilize pharmaceutical processing equipment and clean rooms. In October 2001, the VHP technology was adapted to decontaminate two anthrax-contaminated buildings in the Washington, DC area. In 2002, Steris subsidiary Strategic Technology Enterprises (STE) and the U.S. Army Edgewood Chemical and Biological Center (ECBC) began the process to co-develop a modified VHP (mVHP) capable of biological and chemical decontamination. Over the past few years, the mVHP fumigant has been significantly improved for the decontamination of materials contaminated with chemical agents VX, GD, and HD. During this time, the mVHP system was also improved to enable better distribution and higher concentrations. The mVHP technology is widely scalable and adaptable to accommodate wide range of applications such as buildings, aircraft, and sensitive equipment. Many programs were executed during this time to demonstrate application and determine agent efficacy. Several demonstrations were successfully completed showing large-venue applications and efficacy against agent surrogates. The biological chambers and a bio safety level three (BSL-3) laboratory tests were to determine the decontamination efficacy against both biological agent and surrogate on operationally relevant materials. The chemical chambers work was to determine the decontamination efficacy against chemical agents HD, VX, TGD, and GD on operationally relevant materials. This biological chambers and BSL-3 laboratory work is the subject of this report.

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PREFACE

The work described in this report was authorized under Contract No. W9115R-04-C-0024, "Mobilization of Three VHP-CB Systems and Evaluation of Impact of Materials on VHP-CB Concentration, Half-Life and Adsorption." This work was started in October 2005 and completed in March 2006.

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- Andrew Janick for operating and maintaining the mVHP equipments.
- Iain McVey and Michael Bacik (Strategic Technology Enterprises) for their expert assistance during the engineering testing phase of the program.

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EVALUATION OF THE STERIS SENSITIVE EQUIPMENT DECONTAMINATION (SED) APPARATUS ON A 463L PALLET

1. INTRODUCTION

The STERIS Vaporous Hydrogen Peroxide (VHP®) technology has been used for more than a decade to sterilize pharmaceutical processing equipment and clean rooms.[1,2] In Oct. 2001, the VHP technology was adapted to decontaminate two anthrax-contaminated buildings in the Washington, D.C. area. In 2002, STERIS Corporation, Inc. subsidiary, Strategic Technology Enterprises (STE), and the Edgewood Chemical Biological Center (ECBC) began the process to co-develop a modified VHP (mVHP) capable of both biological and chemical decontamination. Over the past few years, the mVHP fumigant has been significantly improved for the decontamination of materials contaminated with chemical agents VX, GD and HD.[3] The mVHP technology was developed and patented through a Cooperative Research and Development Agreement (CRADA) between ECBC and STE. During this time, the mVHP system was also improved to enable better distribution and higher concentrations. The mVHP technology is scalable and adaptable to accommodate wide range of applications such as buildings, aircraft and sensitive equipment. Many programs were executed during this time to demonstrate application and determine agent efficacy.[4] The modular mVHP™ system was successfully demonstrated in a former office building decontamination tests at the Aberdeen Proving Grounds (APG) in Maryland and C-141B aircraft decontamination tests at Davis-Monthan AFB in Arizona.[5-7] The biological chambers and BSL-3 laboratory work was performed to determine the decontamination efficacy against both biological agent and surrogate on operationally relevant materials. The chemical chambers work was performed to determine the decontamination efficacy against chemical agents HD, VX, TGD and GD on operationally relevant materials.[8,9] The VHP/mVHP decontamination tests and demonstrations are part of a congressionally funded joint venture between ECBC and STE.

In 2004, a VHP decontamination chamber study utilizing a modified SAMS box showed biological simulant could be decontaminated on sensitive equipment within four hours. This finding was the first significant step toward the application of the mVHP technology to the Joint Service Sensitive Equipment Decontamination (JSSED) program. In June 2005, a sensitive equipment decontamination (SED) prototype was evaluated for operationally utility at the Decontamination Limited Objective Experiment (LOE) at Tyndall AFB. The LOE formal report indicated that mVHP has potential applicability for thorough decon of sensitive equipment primarily in rear echelon applications as currently configured on the 463L pallet. Following the LOE, the SED prototype was brought to full decontamination capability. The operational SED prototype was sent to ECBC for both sensitive equipment surrogates and biological surrogate decontamination efficacy evaluations.[10] The prototype utilized mVHP for chemical- and biological-agent decontamination application, improved fumigant distribution and delivery methods. The improved methods enabled higher concentrations in field applications. The approach for the chamber chemical agent and biological surrogate testing was to construct a replica of the SED prototype decontamination chamber for use under engineering controls. The use of the replica enabled a complete evaluation of the Steris

mVHP technology: mVHP fumigant, distribution and operating conditions. The replica provided an additional advantage as a tie-point from lab (agent) to field (surrogate) data. The Steris Sensitive Equipment Decontamination Prototype on a 463L Pallet is referred to as the SED prototype throughout this document.

The primary objective of this test was to determine the mVHP system ability to decontaminate representative articles of sensitive equipment and operationally relevant materials for both biological-warfare agent surrogate contamination. A replica of the SED prototype decontamination chamber was constructed for use under engineering controls for live chemical agent evaluation.[8,9] The biological-efficacy coupon and equipment tests were to address the decontamination efficacy. The decontamination efficacy was compared to the Key Performance Parameters (KPPs) stated in the Operational Requirements Document (ORD) for Joint Service Sensitive Equipment Decontamination (JSSED).[11] The secondary objective of this testing was to evaluate the impact of fumigant on the operability of the representative sensitive equipment. The third objective was to determine the number of representative sensitive equipment articles that could be decontaminated in using the SED prototype in the current configuration. The tests were performed between October 2005 and March 2006 in a space provided by the 20th support command at the Edgewood Chemical Biological Center, APG, Maryland.

1.1 Summary of Conclusions

The purpose of this test was to evaluate the Steris SED prototype. The summary of conclusions is provided in the bulleted list.

- The SED prototype system, as received, demonstrated the ability to decontaminate representative sensitive equipment (e.g. radios, night vision units, GPS units, M40 mask and DVD players) with the potential to meet CCD requirements with either system optimization or longer treatment times.
- As configured, the SED prototype uses approximately 140- to 170-grams of 35% hydrogen peroxide solution per hour. (Section 3.9)
- The SED prototype, as-received, could accommodate 300 individual items and maintain fumigant distribution (Section 3.5.3).
- Representative items of sensitive equipment were exposed to repeated mVHP cycles. All items remained functional, only observations were cosmetic. (Section 3.6)
    - * DVD player anti-glare adhesive bubbled
    - * Radio product information label bubbled
    - * M40 mask anodized metal discolored
- The mVHP SED prototype demonstrates the potential to decontaminate biological contamination on Chemical Agent Resistant Coating (CARC)-coated metal, glass, polycarbonate and silicone and meet both the JPID and JSSED ORD requirements. (Section 3.4.1)
    - * Thirty minutes of mVHP exposure at 500-ppm hydrogen peroxide and 30-ppm ammonia was sufficient to achieve an ORD-equivalent six-log reduction in viable *Geobacillus stearothermophilus* spores for glass, silicone and polycarbonate.

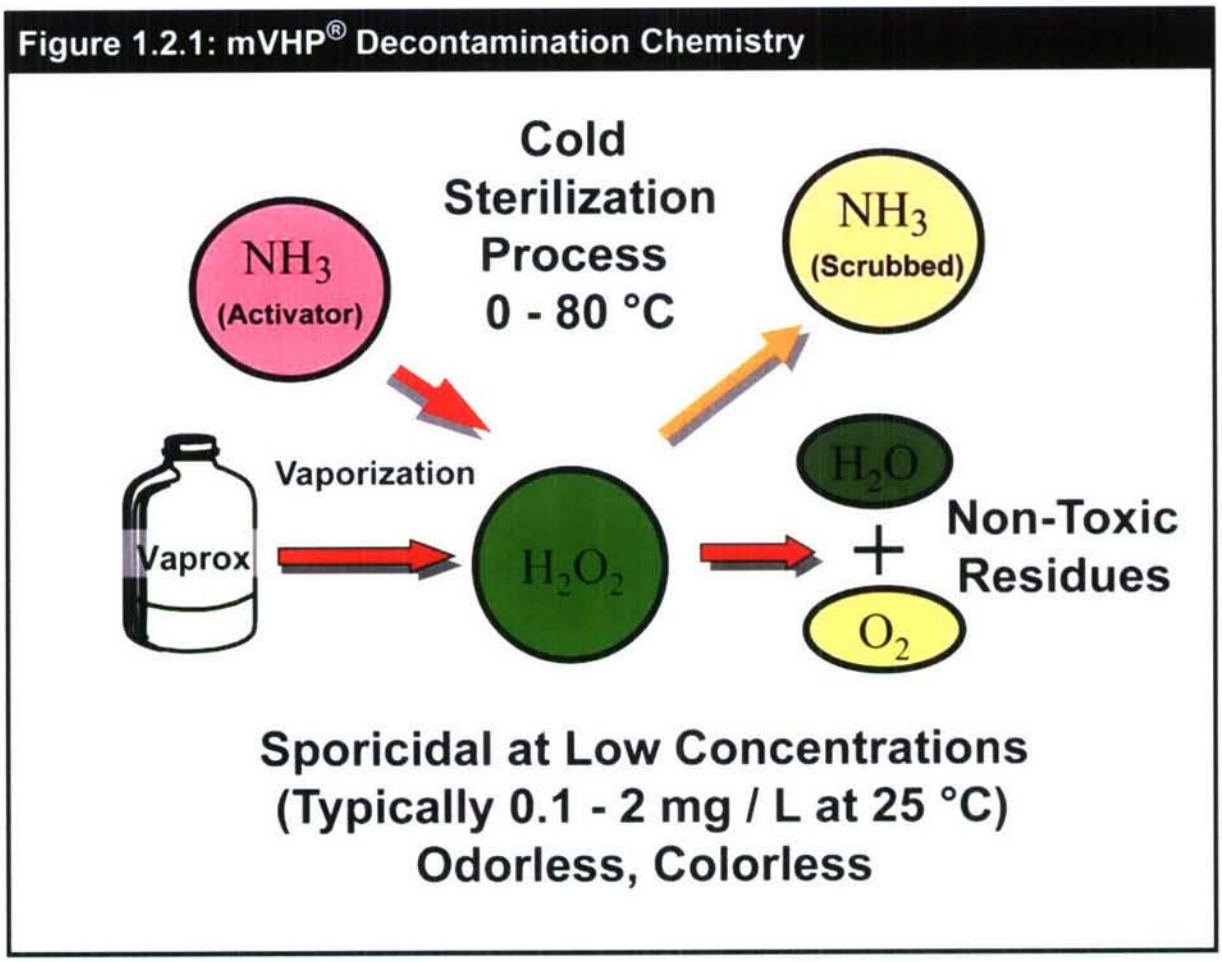
    - Chemical Agent Resistant Coating (CARC) coated metal coupons required a slightly longer time closer to 60-minutes to achieve the same six-log reduction in viable *G. stearothermophilus* spores.
- *B. anthracis* Ames decontamination tests met the ORD equivalent 6-log reduction in viable spores within 5-minutes of mVHP treatment at 500-ppm hydrogen peroxide and 30-ppm ammonia on operationally relevant materials. (Section 3.4.5)
- The baseline (no fumigant) and low concentration (250-ppm hydrogen peroxide and 15-ppm ammonia) results did not meet the ORD equivalent 6-log reduction which was expected. (Sections 3.4.3, 3.4.4)
- The low-fumigant concentration (250-ppm hydrogen peroxide, 15-ppm ammonia) results showed that decon chamber temperature, humidity, air flow, and sample transport did not result in the loss of spores during the efficacy test. By reducing the fumigant concentration, a larger number of viable spores were recovered. The low-fumigant concentration test provided a secondary confirmation that the reduction of viable spores observed during the efficacy test was due to the mVHP fumigant concentration. (Section 3.4.3)
- The baseline results showed that decon chamber temperature, humidity, air flow, and sample transport did not result in the loss of spores. The baseline test provided a secondary confirmation that the reduction of viable spores observed during the efficacy test was due to the mVHP fumigant and not to airflow or handling. (Section 3.4.4)
- The time required to achieve a six-log reduction for *B. anthracis* is far shorter than for *G. stearothermophilus* showing the more conservative nature of *G. stearothermophilus* as an indicator of rendering *B. anthracis* spores nonviable.
- The prototype as received had a high hydrogen peroxide demand which is believed to be due to a material of construction demand. Recommendation for future systems is a material demand study to determine best materials of construction. (Section 3.10)
- The loading test results indicate that there is a potential of decontaminating up to 300 biological contaminated items in the as-received shelf configuration in two hours. Improvements in aeration process have potential to reduce the time to one hour.
- A statistical analysis of the chamber test Lexan replica data and the SED prototype data demonstrated that the Lexan replica is statistically equivalent to the SED system prototype. (Section 3.12)

1.2 The mVHP® Decontamination Process

mVHP is a broad spectrum decontaminant composed of vaporous hydrogen peroxide and a small amount of ammonia gas used within a specified set of conditions. The mVHP decontamination process evaluated is the combination of the patented mVHP decontaminant and decontamination operating conditions.[12,13]

The mVHP decontamination process has been shown effective at atmospheric pressure and at ambient temperatures. The process is completely vapor phase hydrogen peroxide and ammonia. Hydrogen peroxide vapor readily forms hydroxyl free radicals that have been found to react with various micromolecules. VHP rapidly decomposes into two environmentally benign products: oxygen and water vapor (Figure 1.2.1). Metal oxide catalysts are used for large-scale, one-through processes requiring more rapid decomposition on the exhaust stream. The current processes uses up to 30 ppm of ammonia which is below the Permissible Exposure Limit (PEL) of 50 ppm. Unreacted ammonia is scrubbed out of the exhaust air through an appropriate filter. The large systems monitor the exhaust for both ammonia and hydrogen peroxide to ensure no fumigant post the filter bed.

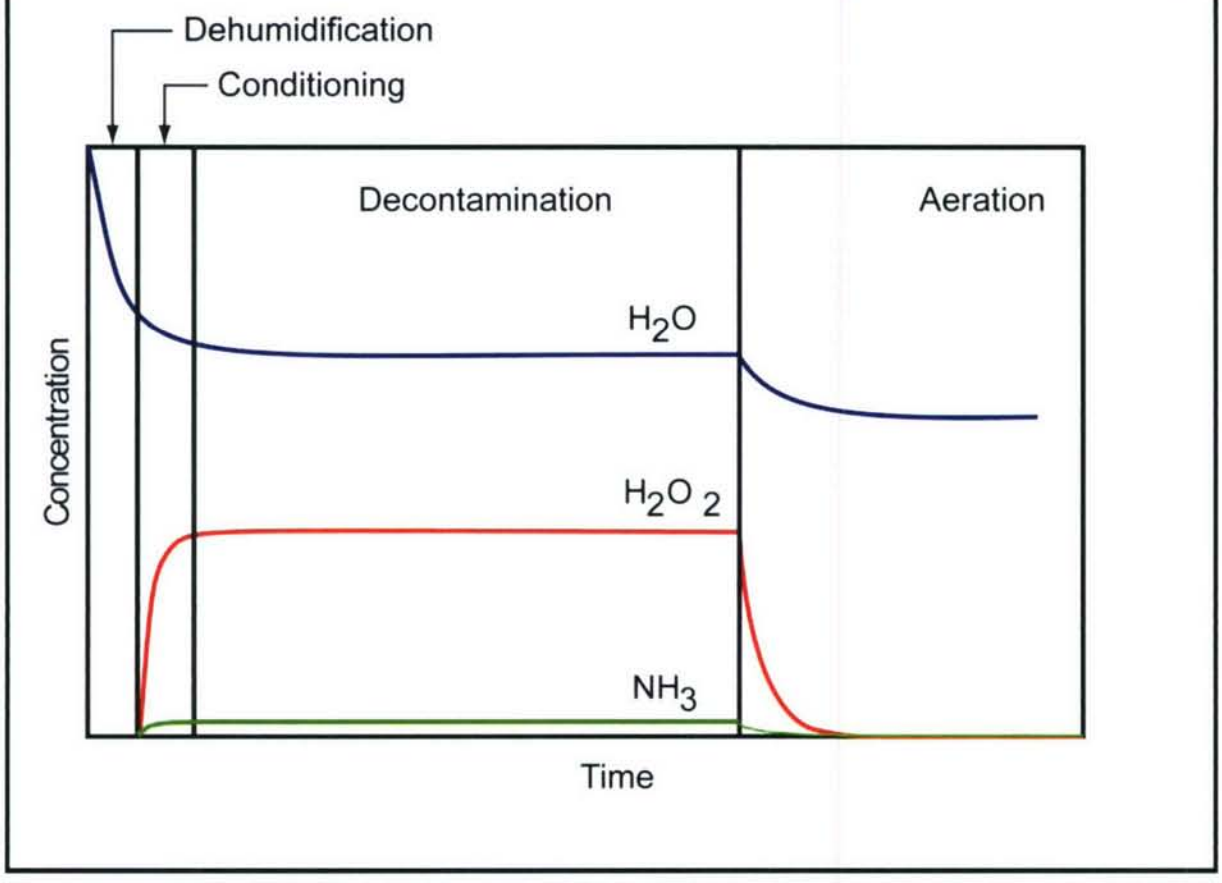
Figure 1.2.1: mVHP® Decontamination Chemistry



Since mVHP is a vapor technique, the primary requirement for decontamination is an enclosure. The technology is versatile - adaptable to enclosures ranging from defined boxes (e.g. SED), to vehicle and building interiors, to tents.[4,14]

Decontamination of an interior/enclosed space using the modular mVHP system is a four-phase process involving preparation of the interior air (dehumidification), achieving a steady state decontaminant level (conditioning), performing the decontamination, and then aerating the space for safe entry (Figure 1.2.2).

Figure 1.2.2: mVHP® Decontamination Cycle



Dehumidification

Hydrogen peroxide vapor can co-condense with water vapor producing an undesired condensate high in hydrogen peroxide. If ambient conditions are likely to permit condensation – high humidity and/or cold temperatures – this can be prevented by circulating dry, heated air through the interior prior to injection of the hydrogen peroxide vapor. The target humidity level is determined by the concentration of vapor to be injected and the desired steady state

concentration for the decontamination. The lower relative humidity permits a higher concentration of hydrogen peroxide without reaching a saturation point.

Conditioning
During the conditioning phase, injection of ammonia and hydrogen peroxide vapor is initiated. Injection rates are selected to rapidly raise the concentrations to the desired set point without condensation. Internal sensors measure and report the ammonia and hydrogen peroxide concentrations to the control system. When the concentrations reach the set point values, the ammonia and hydrogen peroxide injection rates are lowered to maintain the set-point concentrations. Once all the interior monitors reach or exceed the set point concentration, the system proceeds to the next phase.

Decontamination
Decontamination is a timed-phase dependent on the hydrogen peroxide vapor concentration, ammonia vapor concentration and temperature. A decontamination timer counts down from the preset decontamination time. If the concentrations or temperature values fall below the set point, the timer stops. This ensures that during the decontamination phase, the interior space is exposed to at least the minimum decontamination conditions for the desired exposure time.

Aeration
After completion of the decontamination phase, the system stops injection of hydrogen peroxide and ammonia and introduces only dried air into the building. The dried air displaces the hydrogen peroxide and ammonia. The hydrogen peroxide and ammonia are removed by the exhaust system. Samples are drawn and tested from the exhaust system upstream of the catalyst destroyer. When the measurements are below the ammonia and hydrogen peroxide PELs, the user terminates the aeration process.

2. METHODS AND PROCEDURES

2.1 Sensitive Equipment Prototype

Steris provided the Sensitive Equipment Decontamination Prototype on the 463L Pallet for testing at ECBC (Figure 2.1a). The SED prototype measures 8-ft tall by 9-ft long by 7-ft 4-in. wide. The SED prototype is operated through a side entry door (Figure 2.1b). The dehumidifier, fumigant generator, hydrogen peroxide, ammonia, and exhaust filters are compactly built into the unit (Figure 2.1c). The prototype was configured to operate from land power for the testing. The Steris design for the field unit would also contain a generator in the mechanical area. The decontamination chamber is accessed through two side doors. The decontamination chamber measures 7-ft 6-in tall by 8-ft 4-in long by 4-ft wide. The SED prototype is designed to fit into a hot – cold line with separate access for the dirty and clean sides (Figure 2.1a,d). The SED prototype contains a stainless steel rack for the placement of items for decontamination. The rack is adjustable and can be configured to the type of the articles being treated. The SED prototype was received with a 5-shelf cart. The shelves were not adjusted during the loading spacing test. The biological coupon and test article tests were performed using a set of plastic shelving. The SED prototype was fitted with two ATI sensor arrays (Figure 2.1e). Each array contained a 0-2000 ppm hydrogen peroxide sensor, 0-100 ppm ammonia sensor, temperature sensor and relative humidity sensor. One sensor array was mounted on the decontamination chamber wall near the top above the inlet port. The second sensor array was mounted to the shelving unit to measure the conditions at the middle shelf where test articles and coupons were placed. Fumigant was distributed in the decontamination chamber by 16 small fans mounted to the decontamination chamber walls (Figure 2.1f).

2.2 Test Materials

The selected test materials span a variety of structural and functional materials common to aircraft, vehicles, protective- and sensitive-equipment that encompass a variety of material properties, compositions and porosities. The test materials include bare aluminum, CARC-painted aluminum, AF-topcoat-painted aluminum, glass, polycarbonate, Viton®, Kapton® and silicone (Figure 2.2). The biological agent surrogate test coupons are 1.3 cm squares, except glass, which is round. The chemical agent test coupons are 2-inch circular disks with a surface area of 3.14 in^2 (20.27 cm^2).[8] The glass chemical agent test coupons were ordered pre-cut from McMaster-Carr. All other chemical and biological test coupons were cut from stock material. Uniformity is assured by obtaining a large enough quantity of material that multiple test samples can be prepared with uniform characteristics (e.g., test coupons will all be cut from the interior rather than the edge of a large piece of material). All coupons are stored in zip-tight bags in containers in order to prevent/limit contact with foreign substances until the coupons are needed for testing. The biological test coupons were sterilized prior to use. The coupon preparation information including material vendors and descriptions is provided in Appendix A.

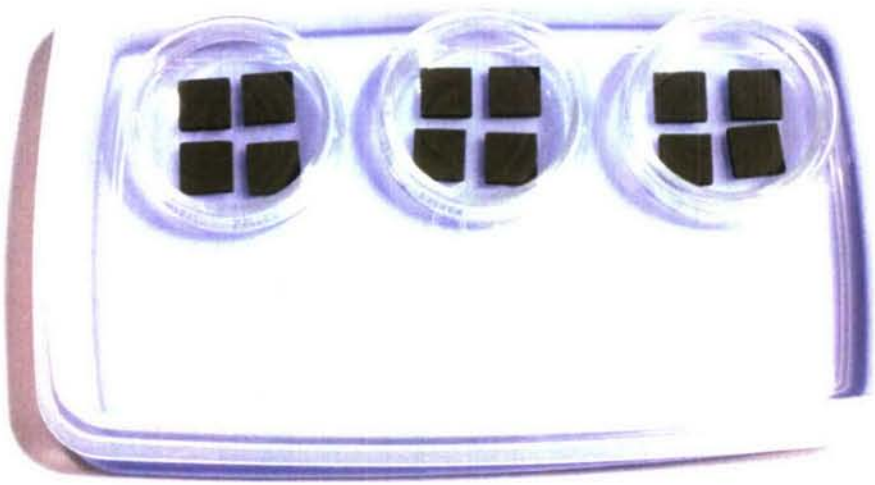
Figure 2.1: Steris Sensitive Equipment Decontamination Prototype

Figure 2.2: Chemical and Biological Test Coupons

2.3 Biological Spore Inoculated Test Coupons

G. stearothermophilus spore stocks were purchased from Apex Laboratories, Apex NC 27502 (lot 329251 and product number LPT-606). Coupons were sterilized in small Petri dishes with wire mesh screens in groups of 4 per dish. They were autoclaved for 25 minutes at 121 °C and 15 psi. Once the Petri dishes were cooled, the surface of each coupon was inoculated with a 10-µL volume 1 x 10^6, 1 x 10^7, or 1 x 10^8 spores in water. The spore-inoculated coupons were left in a bio safety level two hood until they appeared visibly dry prior to testing. Once dry, the dishes with coupons were transferred to Tupperware containers and transported to the chamber for experiments. After the exposure, samples were transported back to the laboratory in Tupperware containers. One of each coupon type for each timepoint were aseptically transferred to 5 mL Tryptic Soy Broth (TSB) and incubated at 55 °C. Coupons were observed daily for 7 days. If positive growth was detected (turbid broth) the remaining 3 coupons were processed. Coupons were aseptically placed in 5 mL buffered peptone water with 0.01% Tween 80 and sonicated for 10 minutes. Following sonication, 10 µl of Antifoam 289 was added and samples were vortexed at maximum speed for 2 minutes. Samples were then serially diluted in buffered peptone water and pour plated (1 mL per plate) using Tryptic Soy Agar (TSA). Plates were gently swirled in each direction and allowed to solidify in a biosafety cabinet. Once solidified, plates were transferred to a 55 °C incubator overnight. Resultant colonies were enumerated the following day. A representation of the biological coupons in Petri dishes and Tupperware containers is shown in Figure 2.4.

Figure 2.3: Example of Biological Coupon for Testing



2.4 Biological Indicators

Commercial *G. stearothermophilus* spore biological indicators (BIs) functioned as a confirmatory test for sporicidal effectiveness. The commercial BIs, inoculated to a level of approximately 10^6 colony forming units (CFUs), were purchased from two vendors, Apex (ATCC 12980, Lot H2165 Exp. 31 March 06) and STERIS (ATCC 7953, Lot 1885B Exp. April 7, 06). *G. stearothermophilus* was specifically selected for testing since it is a spore forming bacterium that has been identified as an appropriate conservative surrogate for *B. anthracis* with the VHP technology. After exposure, BIs were transported back to the laboratory with coupons in Tupperware containers. In the laboratory, BIs were aseptically transferred to 5 mL TSB broth and incubated for 7 days at 55 °C. Samples were checked daily and considered non-viable after 7 days if no turbidity (growth) was observed.

2.5 Biological Surrogate Inoculated Equipment Test Preparation and Analysis Methods

Coupons Enumeration: *G. stearothermophilus* spore stocks were purchased from Steris Corporation at a concentration of 2.2 x 10^7 spores in 100-uL solution. Coupons were sterilized in sterile glass bottles. Each group of coupons was segregated according to type. They were autoclaved for 25 minutes at 121 °C and 15 psi. Success of sterilization was determined by temperature sensitive autoclave tape. Upon successful completion of the sterilization cycle, the coupons were placed in a biosafety cabinet and four (4) of each type were placed in sterile petri dishes. Each coupon was inoculated with 10 uL of spore stock to make a 2.2 x 10^6 inoculation. The spore-inoculated coupons were left in a BSL-2 hood until they appeared visibly dry prior to testing. Once dry, the dishes were covered, labeled and separated according to type and test iteration. Coupons were transferred to secure containers until testing day. Coupons were transported to the SED box in Tupperware containers. After the exposure, samples were transported back to laboratory in the same Tupperware containers. Each coupon of each coupon type was aseptically transferred to 2.0 mL Phosphate Buffered Saline with 0.01% Tween 80. The samples were allowed to sit for 20 minutes and were vortexed for 30 seconds every five minutes. Samples were then serially diluted in the same PBS buffer solution and pour plated (1 mL per plate) using Tryptic Soy Agar (TSA). Plates were labeled according to sample location and dilution and were gently swirled in each direction and allowed to solidify in biosafety cabinet. Once solidified, plates were transferred to a 55 °C incubator. Resultant colonies were enumerated at 24- and 48-hour time periods. The 48-hour colony count was used for reporting purposes.

Swabbing Enumeration: *G. stearothermophilus* spore stocks were purchased from Steris Corporations at a concentration of 2.2 x 10^7 spores in 100-uL solution. The test article inoculation locations were identified by the test director. Items were cleaned with 10% Bleach solution and then wiped with a 70% ethanol solution. Areas of inoculation were indicated with a black circle. The items were placed in a biosafety cabinet. Each item was inoculated with 10 uL of spore stock to make a2.2 x 10^6 inoculation. The spore-inoculated items were left in a BSL-2 hood until they appeared visibly dry prior to testing. Dryness was indicated by a white spot forming on the site where the inoculation was made. Once dry, the items were covered and prepared for transport to the test site. Items were transferred into a clean 3-mil ziplock bag and transported to the SED box in a Nalgene tub. After the exposure,

samples were transported back to the laboratory in same set of containers. For each inoculated item, a wet swab with sterile PBS with 0.01% Tween 80 was used to swab the areas inside the ink circle. These swabs were placed in 1.0 mL of PBS with 0.01% Tween 80. The swabs were allowed to sit for 20 minutes with vortexing for 30 seconds every five minutes. Samples were then serially diluted in the same PBS buffer solution and pour plated (1 mL per plate) using TSA. Plates were labeled according to unique sample item number and dilution, and were gently swirled in each direction and allowed to solidify in a biosafety cabinet. Once solidified, plates were transferred to a 55 °C incubator. Resultant colonies were enumerated at 24- and 48-hour time periods. The 48-hour colony count was used for reporting purposes.

Four locations were selected on each biological contamination test article for the placement of the spores. Different locations were used for each test for two primary reasons. First, using new locations would enable the evaluation of the different types of surfaces on pieces of equipment such as screen, buttons and plastic casing. Second, the use of new locations for each test would reduce potential for cross-contamination between tests. The test items contaminated with biological spores included DVD players, GPS units, night vision monocular units and radios. The contamination areas were shown in Figure 2.5.

Figure 2.5: Biological Spore on Equipment Contamination Areas

2.6 Chemical Indicator Strips

Chemical indicators (CIs) sensitive to vaporous hydrogen peroxide are regularly used by healthcare facilities for confirmation that the conditions required for sterilization have been achieved within a sterilizer. The chemical indicators were used throughout the VHP / mVHP programs to verify that fumigant was delivered to key places within the interior space. Most programs used CIs during the initial engineering tests. The CIs served as a confirmation that fumigant was delivered to the coupon trays for each chamber test. The SED prototype test utilized CIs in a variety of tests. The CI's were used to check distribution and performance during early engineering and troubleshooting tests. The CIs were also used during the loading

density tests to assess fumigant distribution at high loading densities. Two brands of strips were used. Browne H2O2 Vapour Strips (model EN 867-1, lot 012222 expiration date 07/2007, lot 009950, expiration date 11/2005) were used for the loading, troubleshooting and engineering tests. Steris VHP Indicator (model NB305, lot 227519/1/A, exp. 6/1/2007) were used mainly for troubleshooting and engineering tests. A limited number of the Steris strips were used during the loading tests.

2.7 Decontamination Efficacy Targets

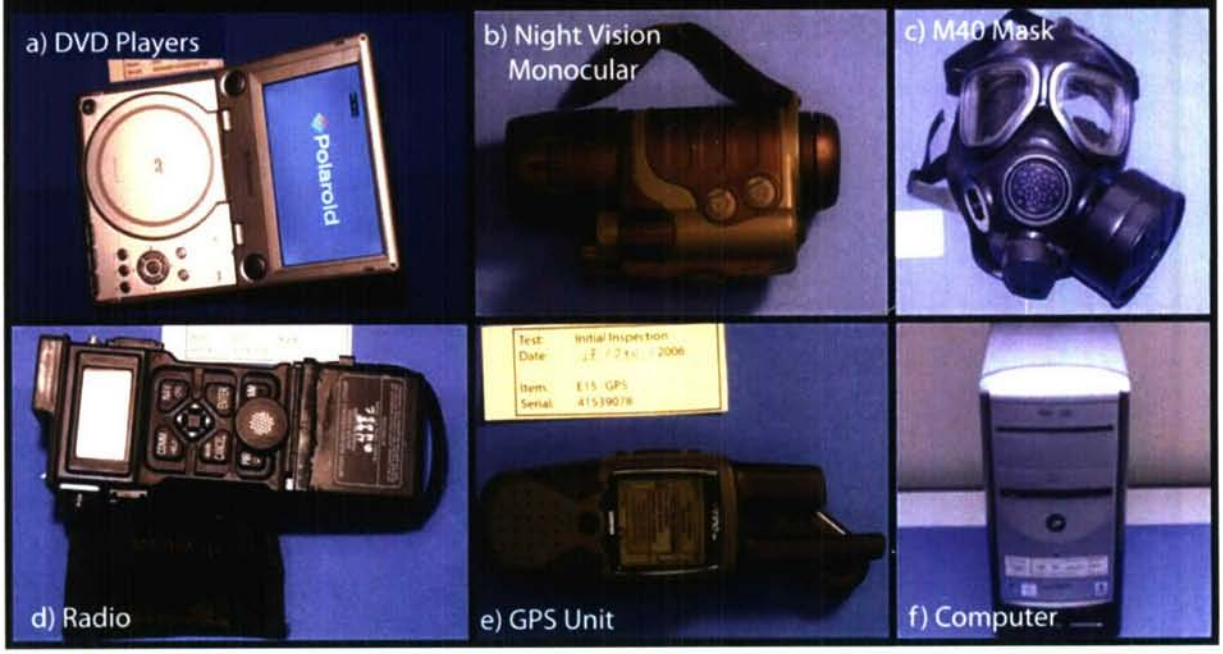
The determination of decontamination efficacy is measured by quantifying the amount of agent (or surrogate) remaining after a decontamination process and comparing to the agent (or surrogate) starting amount. The decontamination efficacy value can typically be expressed in terms of the percent agent (or surrogate) reduction resulting from the decontamination process. The mVHP technology study has evaluated the potential application of the technology to interior decontamination. In May 2005, the Joint Platform Interior Decontamination (JPID) Operational Requirements Document (ORD) was issued specifying threshold and objective key performance parameters (KPP) for thorough decontamination efficacy for chemical vapor- and contact-hazards, and biological agent residual levels.[15] In spring 2005, the development of the SED prototype added the evaluation of the technology for the potential application to sensitive equipment. The potential application to sensitive equipment falls under the ORD for the Joint Service Sensitive Equipment Decontamination (JSSED) program Joint Service Interior Decontamination (JSID) document. The JSSED ORD document also specifies specifies threshold and objective KPPs for thorough decontamination efficacy for chemical vapor and contact hazards and biological agent residual levels.[11] The JPID and JSSED ORD KPP values are listed in Table 2.7. The evaluation results were compared to both ORD KPPs as applicable.

Table 2.7: Operational Requirements Document (ORD) Key Performance Parameters (KPP)				
VAPOR HAZARD	**Starting Challenge**	**Nerve - G**	**Nerve - V**	**Blister - H**
JPID Threshold Vapor Level	1 g/m^2	< 0.00087 mg/m^3	< 0.000036 mg/m^3	< 0.0058 mg/m^3
JPID Objective Vapor Level	1 g/m^2	< 0.0002 mg/m^3	< 0.000024 mg/m^3	< 0.003 mg/m^3
JSSED Threshold Vapor Level	10 g/m^2	< 0.1 mg/m^3	< 0.04 mg/m^3	< 0.1 mg/m^3
JSSED Objective Vapor Level	10 g/m^2	< 0.0001 mg/m^3	< 0.00001 mg/m^3	< 0.003 mg/m^3
CONTACT HAZARD	**Starting Challenge**	**Nerve - G**	**Nerve - V**	**Blister - H**
JPID Threshold Exposure Level	1 g/m^2	< 1.7 mg/m^2	< 0.04 mg/m^2	< 3.0 mg/m^2
JPID Objective Exposure Level	1 g/m^2	0.0 mg/m^2	0.00 mg/m^2	0.0 mg/m^2
JSSED Objective Exposure Level	10 g/m^2	< 16.7 mg/m^2	< 0.78 mg/m^2	< 100 mg/m^2
BIOLOGICAL	**Starting Challenge**	**Bacterial Endospores**	**Vegetative Bacteria**	**Viruses**
JPID Threshold Reduction	$1x10^8$ CFU/m^2	< 100 CFU/m^2	< 10 CFU/m^2	< 10 PFU/m^2
JSSED Objective Reduction	Not specified	< 100 CFU/m^2	< 10 CFU/m^2	< 10 PFU/m^2

2.8 Articles of Sensitive Equipment

The sensitive equipment exposure tests were conducted to determine the impact of repeated mVHP decontaminant exposures on visual appearance and, for some items, operational function. The test articles included six DVD players, four radios, four night vision monocular (NVM) units, five GPS units, one M40 mask and one desktop personal computer (PC). The six DVD players are Polaroid DVD Players, Model PDM-0711. The four radios are A/N-PRQ-7 Radio Sets. The four Night Vision Monoculars tested were Yukon CE Model NV-MT2 24022, 3 x 42-power, made in Russia. The five GPS units provided for testing were all Garmin Rino 120 models. The PC used in this test had been previously been exposed to the fumigant mixture during testing on the fumigation of the interior of a C-141 Starlifter aircraft at Davis-Monthan AFB, Arizona. One production test model of a CB Protective Respirator, M40 series, with C2 Filter Canister were provided. A representative photograph of the each group of items studied is provided in Figure 2.8. The detailed photograph inspections are provided in Appendix C.

Figure 2.8: Representative Articles of Sensitive Equipment



2.9 Sensitive Equipment Inspection

DVD Players: Prior to testing, each DVD article underwent comprehensive physical and operational inspections. Each article was initially photographed to determine prior damage and functionality. Following IOP DS05003, *Visual Inspection and Operation Evaluation of Test Articles: DVD players*, inspectors performed an initial physical inspection consisting of noting any wear, rough spots, discoloration, cracking, or other damages on the DVD case. Any damages to the DVD screen, including peeling, were noted. Inspectors noted damages to the battery connectors including possible corrosion. Lastly, inspectors ensured that all buttons remained resilient following depression. Following the physical inspection, inspectors performed operational tests including: ability to power up using AC or DC power, ability to load DVD, ability to advance scenes, and functionality of speakers and headphone jack. Any observed damages were recorded on the DVD mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, each article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

GPS units: Prior to testing, each GPS article underwent comprehensive physical and operational inspections. Each article was initially photographed to determine prior damage and functionality. Following IOP DS05002, *Visual Inspection and Operation Evaluation of Test Articles: GPS units*, inspectors performed an initial physical inspection consisting of noting any wear, rough spots, discoloration, cracking, or other damages on the GPS shell.

Any damages to the GPS screen, including peeling, were noted. Inspectors noted damages to the antenna, which was made of a softer rubber. Lastly, inspectors ensured that all buttons remained resilient following depression, and that the thumbstick moved freely. Following the physical inspection, inspectors performed operational tests including: ability to power up the article, transmit and receive radio communication, ability to triangulate location using satellite and track a change in location, and functionality of speakers. Any observed damages were recorded on the GPS mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, each article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

NVM units: Prior to testing, each NVM article underwent comprehensive physical and operational inspections. Each article was initially photographed to determine prior damage and functionality. Following IOP DS05004, *Visual Inspection and Operation Evaluation of Test Articles: NVM units*, inspectors performed an initial physical inspection consisting of noting any wear, rough spots, discoloration, cracking, or other damages on the NVM shell. Any damages to the NVM lenses, including peeling, were noted. Inspectors noted whether the lenses continued to freely rotate—as necessary for focusing article. Lastly, inspectors ensured that both buttons remained resilient following depression. Following the physical inspection, inspectors performed operational tests to ensure the article's ability to power up and utilize the IR focus. Any observed damages were recorded on the NVM mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, each article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

Radios: Prior to testing, each Radio article underwent comprehensive physical inspections. Due to the nature of the radio's functionality, they were not engaged to prevent inadvertent emergency beaconing. Each article was initially photographed to determine prior damage. Following IOP DS05006, *Visual Inspection and Operation Evaluation of Test Articles: Radio units*, inspectors performed an initial physical inspection consisting of noting any wear, rough spots, discoloration, cracking, or other damages on the Radio shell. Any damages to the Radio screen, including peeling, were noted. Lastly, inspectors ensured that all buttons remained resilient following depression. Any observed damages were recorded on the Radio mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, each article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

M40 Military Mask: Prior to testing, the M40 mask underwent a comprehensive physical inspection. The article was initially photographed to determine prior damage. The mask was inspected according to IOP DS05005, *Visual Inspection and Operation Evaluation of Test Articles: M40 mask units.* Inspectors performed an initial physical inspection noting any wear, rough spots, discoloration, cracking, or other damages on the M40 rubber. Mask webbing was examined to determine any loss in elasticity or cracking. Any damages to the M40 eyepieces, including peeling and scratches, were noted. Careful note was taken as to any damage to the metal voice plate, the metal canister, and the drink tube. Lastly, inspectors ensured that the canister filter could be easily unscrewed. Any observed damages were recorded on the M40 mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, the article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

Desktop computer: Prior to testing, the Computer underwent a comprehensive physical and operational inspection. The article was initially photographed to determine prior damage and functionality. Following IOP DS05009, *Visual Inspection and Operation Evaluation of Test Articles: Computer*, inspectors performed an initial physical inspection consisting of noting any wear, rough spots, discoloration, cracking, or other damages on the Computer case. Any damages to the monitor, including peeling, were noted. Inspectors noted damages to all of the external portions of the CPU, monitor, mouse, and keyboard. Lastly, inspectors ensured that all keyboard buttons remained resilient following depression. Following the physical inspection, inspectors performed operational tests including: ability to power up, ability to load Windows®, and functionality of speakers, keyboard and mouse. Any observed damages were recorded on the Computer mVHP Sensitive Equipment Evaluation data test form. Observed damages were also documented with photographs. This thorough examination was repeated following each mVHP cycle to which the article was subjected. Following the final inspection, the article was photographed showing any changes. A summary of the initial and final inspections is provided in Sections 3.11.2 and 3.11.4, respectively. The initial and final pictures for each test article are provided in Appendix B.

2.10 Types of Testing

The SED prototype evaluation was the combination of several test groups to determine operation, biological efficacy, equipment loading volume and impact on sensitive equipment articles.

Engineering Tests: The engineering tests were conducted during receipt of the unit. The purpose of the engineering tests was to learn system operation and verify operational prior to testing.

Biological Surrogate and Agent Material Recovery Tests: The biological surrogate and agent material recovery tests were conducted prior to the decontamination tests to determine the spore recovery efficiency from the various substrates. No procedure modifications were necessary for the materials used in this test to enable spore recovery efficiency.

Biological Surrogate on Coupon Efficacy Test: The efficacy tests utilize both contaminated coupons and biological indicators. The coupon contamination starting challenge was 1 x 10^6 spores per coupon. The mVHP decontaminant is used. Two efficacy test fumigant concentrations were used: 500-ppm hydrogen peroxide / 30-ppm ammonia and 250-ppm hydrogen peroxide / 15-ppm ammonia. Unlike the chambers test, samples cannot be removed from the actual prototype during the cycle. The SED run lengths selected were based on decontamination time required as determined in chambers test. Control samples evaluated immediately after preparation are identified as "time 0".

Biological Surrogate Baseline Test: The efficacy tests utilize both contaminated coupons and biological indicators. The coupon contamination starting challenge is 1 x 10^6 spores per coupon. The mVHP decontaminant is not used. Air is passed over the coupons for the duration of the test. The baseline provides information regarding the impact of air flow on spore physical removal.

Simulated Sensitive Equipment Exposure Test: The representative items of sensitive equipment were placed through several mVHP decontamination cycles in the SED prototype. All equipment was inspected visually before and after the decontamination. In addition, the functional items (e.g. DVD players, night vision monocular units, GPS units and computer) were tested to determine if operational after each cycle.

Simulated Sensitive Equipment Loading Test: Most items of sensitive equipment are typically small units. The loading test was to determine how many articles could be placed in the SED prototype as configured and still maintain adequate fumigant distribution.

Biological Surrogate on Simulated Sensitive Equipment Efficacy Test: The equipment efficacy tests utilized contaminated DVD players, radios, GPS units and night vision monocular units. In addition, a M40 mask and desktop computer were exposed to fumigant. The coupon contamination starting challenge is 1 x 10^6 spores per test article. The mVHP decontaminant is used. The efficacy test fumigant concentration is 500-ppm hydrogen peroxide and 30-ppm ammonia. Unlike the chambers test, samples cannot be removed from the actual prototype during the cycle. The SED run lengths selected were based on decontamination time required as determined in chambers test. Control samples evaluated immediately after preparation are identified as "time 0".

3. TEST RESULTS AND DISCUSSION

3.1 *G. stearothermophilus* as Suitable *B. anthracis* Surrogate for mVHP

The selection of an appropriate simulant for biological agent warfare decontamination can be strongly influenced by the active component of the decontaminant to be used. A suitable

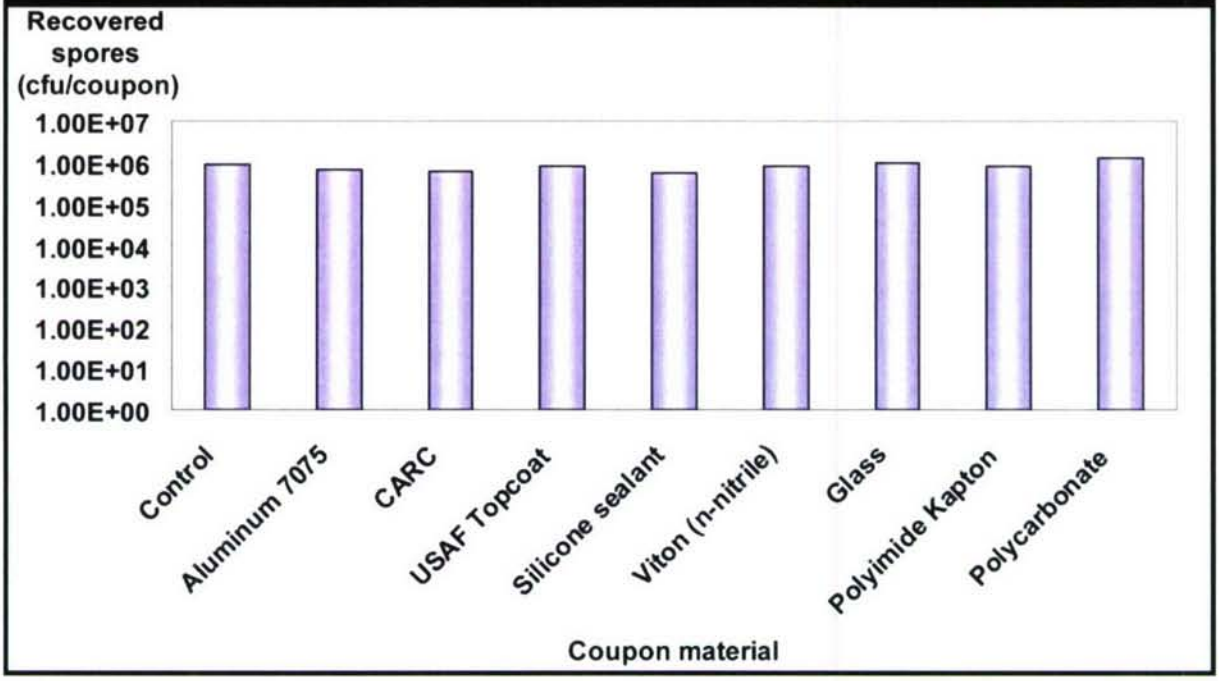
simulant for the mVHP evaluation should react similar to *Bacillus anthracis*. In addition, the simulant should be more conservative than the actual agent. The simulant should be rendered non-viable in either the same time or longer than the actual agent. The same- or delayed-time effect would enable that the determined simulant decontamination cycle times are more than sufficient for the actual agent decontamination.

Laboratory work conducted early in the mVHP test programs addressed the selection of biological simulant in comparison to *B. anthracis* strains. *G. stearothermophilus* was found to be the best simulant for *B. anthracis* with VHP/mVHP.

3.2 Biological Surrogate and Agent Material Recovery Tests

The recovery tests were originally developed based upon a test plan first put in place in February 2003. Organisms were applied to coupon materials in a 5% Fetal Bovine Serum/Buffered Peptone Water solution to simulate bioburden. At the time, a total of 1×10^7 spores in a 10 µl solution were loaded onto coupons because recovery efforts only yielded 1×10^6. The decision was made to load 1×10^7 spores so that 1×10^6 spores would be recovered each time. After further experimentation in the laboratory, an updated recovery method was developed. The FBS was dropped from the inoculum due to discrepancies in the data. The spores were purchased from Apex Laboratories to prevent any inconsistencies in lot to lot variation and 0.01% Tween 80 was added to increase recovery rate. As a result of adding 0.01% Tween 80 to recovery media, the inoculum amount was decreased because almost 100% recovery rate was achieved. The inoculum amount currently used is 1×10^6 spores in 10 µl buffered peptone water per coupon. The averaged results for the material recovery tests are provided in Figure 3.2.1.

Figure 3.2.1: Spore Recovery Results for *G. stearothermophilus*



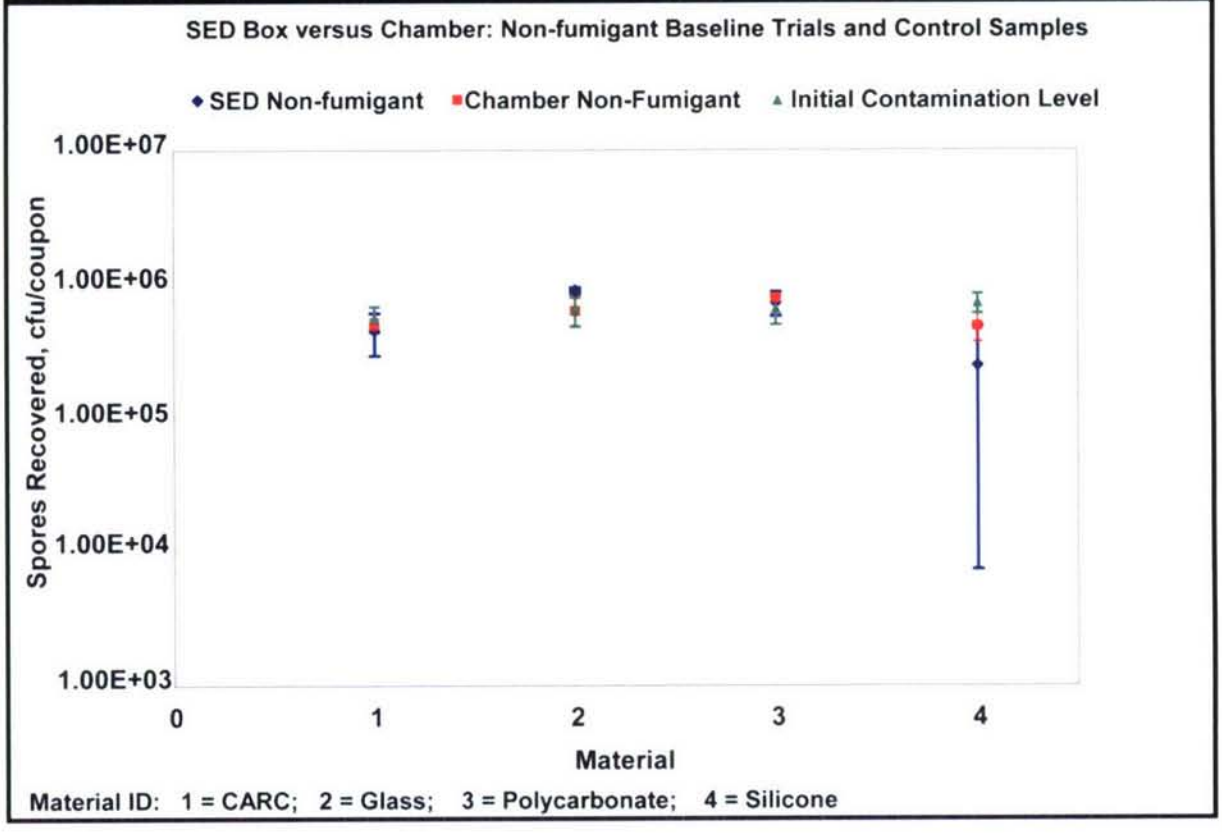
For each test a control set of samples was prepared and kept in the laboratory. The control samples were processed using the same method as the mVHP exposed samples. The results for each control set are shown as "time 0" for each run. The control values show that the recovery method enables a 1×10^6 spore recovery from the coupon surfaces.

The reproducibility of the spore recoveries can be demonstrated by comparing the control samples from the chambers and SED test programs. In addition, the baseline chambers and SED program results were used in this analysis. The results are shown in Figure 3.2.2.

A statistical analysis of the data from the two test chambers was conducted, using the Q-test for statistical outliers, and Student's t-test to compare groups. Within the individual test groups of coupon materials, there were no statistical outliers, despite data scatter that generated standard deviations between 2% (polycarbonate, chamber) and 97% (silicone, SED Box) of the mean value of the concentration.

Student's t-test was calculated using the data from similar coupons in the two chambers to determine if there were statistically significant differences between the performances of the two chambers. For all four coupon materials, the Student's t-test values calculated using the two-tailed, heteroscedastic values with four degrees of freedom are unable to reject the hypothesis that the two data sets are statistically identical at the p=0.1 significance level. Therefore, from the data available, we cannot say that the data sets are statistically different.

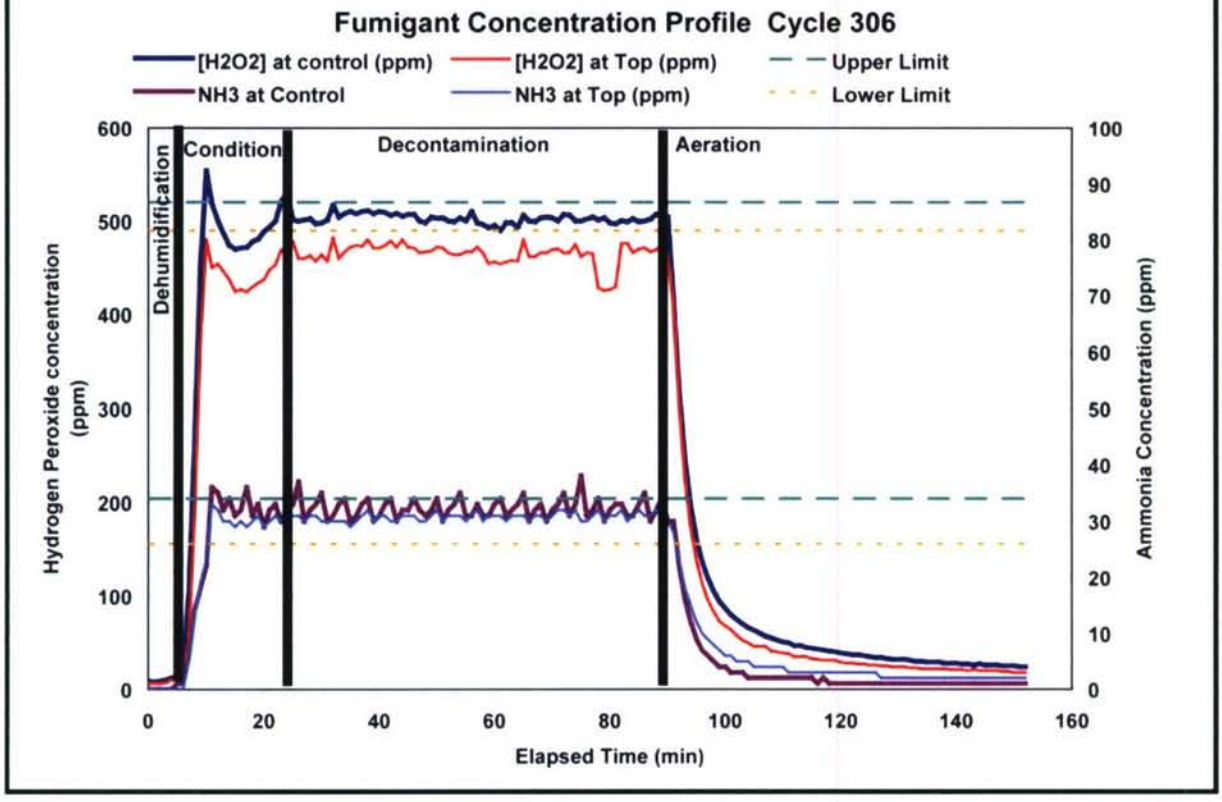
Figure 3.2.2: Reproducible Recoveries from Coupon Materials



3.3 SED Prototype Operation

The SED prototype operation is straight forward. The unit has a computer driven user interface for entering the target fumigant concentrations and phase durations. Once initiated, the prototype conducts the four-phase process from start to finish. The system tracks the actual time to complete each step. For example, if the user would enter 1-minute for the dehumidification process, the system ensures that the target relative humidity is achieved by dehumidifying to the required level before advancing to the next phase. The system can also be programmed with all test information such that only one button needs to be pressed to start the cycle. The time for each phase and total cycle time for these tests is discussed in Section 3.13. An example of a SED decontamination cycle showing the four phases is provided in Figure 3.4. The control charts for each run showing fumigant concentration, temperature, humidity, sample loading and removal are provided in Appendix C.

Figure 3.3: System Operation



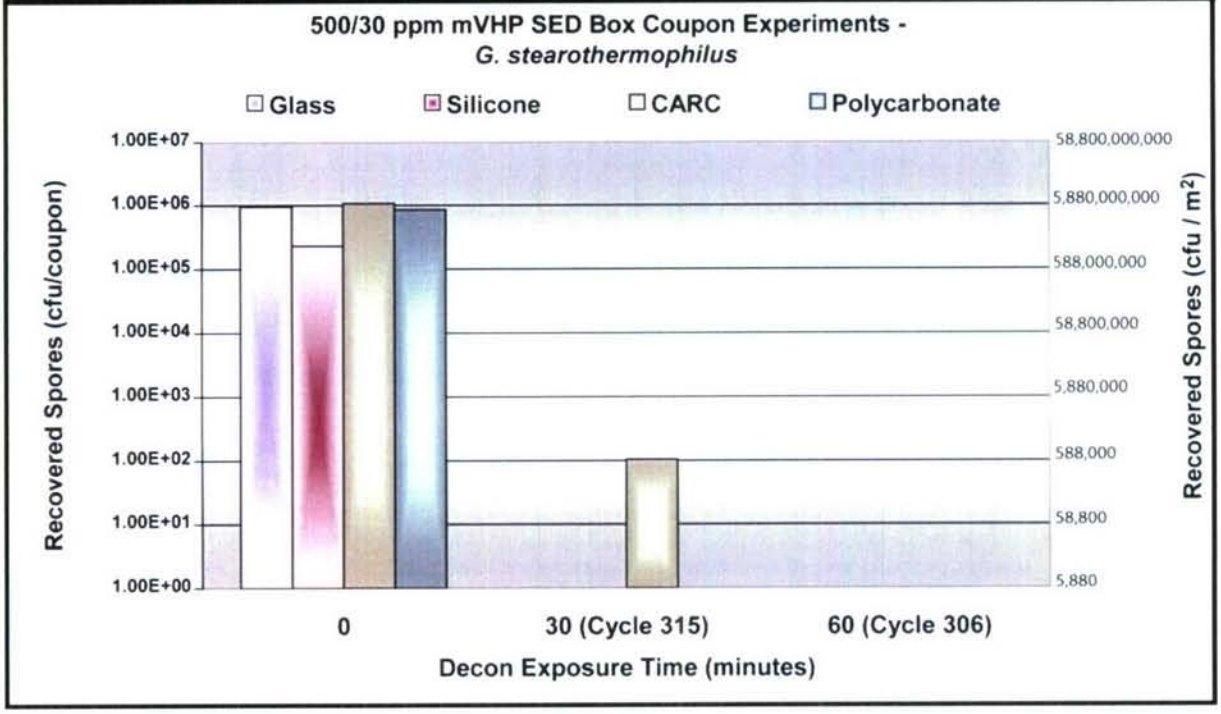
3.4 Biological Surrogate Coupon Tests

3.4.1 Biological Surrogate Efficacy Test Results at Target Concentration

The efficacy tests utilized contaminated coupons. The coupon challenge was 1 x 10^6 spores per coupon which is equivalent to 5.9 x 10^9 cfu/m^2. The mVHP decontaminant was used. The efficacy test target fumigant concentration was 500-ppm hydrogen peroxide and 30-ppm ammonia. The sample collection times were based on the chambers efficacy results. Run 315 is a 30-minute decon phase test. The total CTs for hydrogen peroxide and ammonia were 492 and 32, respectively. The total run length was 103 minutes, with 43 minutes for aeration. Run 306 is a 60-minute decon phase test. The total CTs for hydrogen peroxide and ammonia were 756.3 and 47.3, respectively. The total run length was 152 minutes, with 61 minutes for aeration. The average results for the four replicate coupons are provided in Figure 3.4.1.

The glass, silicone and polycarbonate coupons displayed a 6-log reduction in *G. stearothermophilus* spores in the 30-minute decon phase test. The CARC samples took longer to decontaminate. The coupons showed a 4-log reduction after the 30-minute decon phase test and the complete 6-log reduction during the 60-minute decon phase test.

Figure 3.4.1: Target Concentration Coupon Results

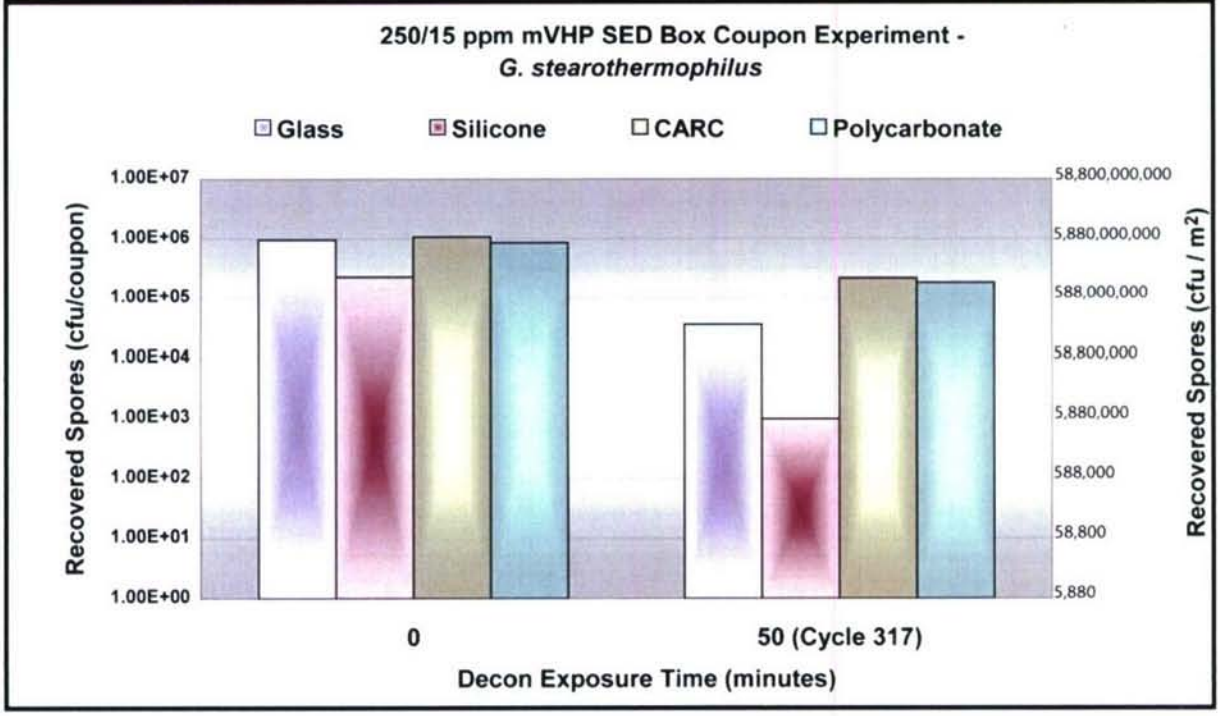


3.4.2 Biological Surrogate Efficacy Tests at Low-Fumigant Concentration

The efficacy tests utilized contaminated coupons. The low-fumigant concentration tests were performed to demonstrate that at lower concentration, higher growth counts are obtained for the same exposure time-points. This low concentration test also provided confidence in the efficacy test results at the target concentration. The coupon challenge was 1×10^6 spores per coupon which is equivalent to 5.9×10^9 cfu/m^2. The mVHP decontaminant was used. The efficacy test fumigant concentrations were 250-ppm hydrogen peroxide and 15-ppm ammonia. The sample collection times were based on the chambers efficacy results. Run 317 is a 50-minute decon phase test. The total CTs for hydrogen peroxide and ammonia were 251 and 20, respectively. The total run length was 115 minutes, with 62 minutes for aeration. The average results for the four replicate coupons are provided in Figure 3.4.2

The glass coupons displayed a 2-log reduction in *G. stearothermophilus* spores. The silicone coupons displayed almost a 2-log reduction in *G. stearothermophilus* spores. The polycarbonate coupons displayed a 1-log reduction in *G. stearothermophilus* spores. The CARC coupons displayed almost a 1-log reduction in *G. stearothermophilus* spores. The reduction in fumigant concentration from 500 / 30 ppm to 250 / 15 ppm has a significant impact on the time required for thorough decontamination.

Figure 3.4.2: Low-Fumigant Concentration Coupon Results

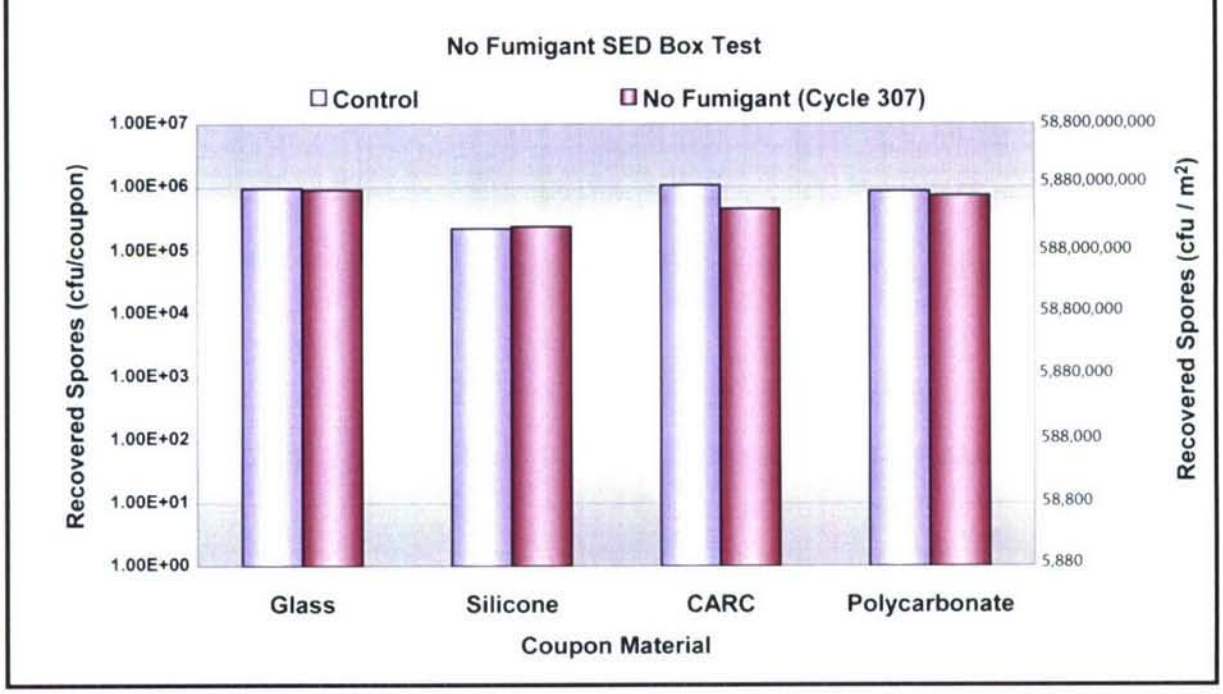


3.4.3 Biological Surrogate Baseline Test

The efficacy tests utilized contaminated coupons. The coupon challenge was 1 x 10^6 spores per coupon which is equivalent to 5.9 x 10^9 cfu/m^2. The mVHP decontaminant was not used. Air is passed over the coupons for the duration of the test. The baseline provides information regarding the impact of air flow on spore removal/survival. The sample collection times were based on the chambers efficacy results. Run 307 is a 60-minute decon phase test. The total CTs for hydrogen peroxide and ammonia were 0 and 0, respectively. The total run length was 101 minutes, with 15 minutes for aeration. The average results for the four replicate coupons are provided in Figure 3.4.3.

The glass, silicone and polycarbonate coupons showed no measurable loss in *G. stearothermophilus* spores as a result of transport, handling and airflow. The CARC samples show the largest delta, but the spore loss observed is within the statistical data as shown in Section 3.2.

Figure 3.4.3: Baseline Test Coupon Results



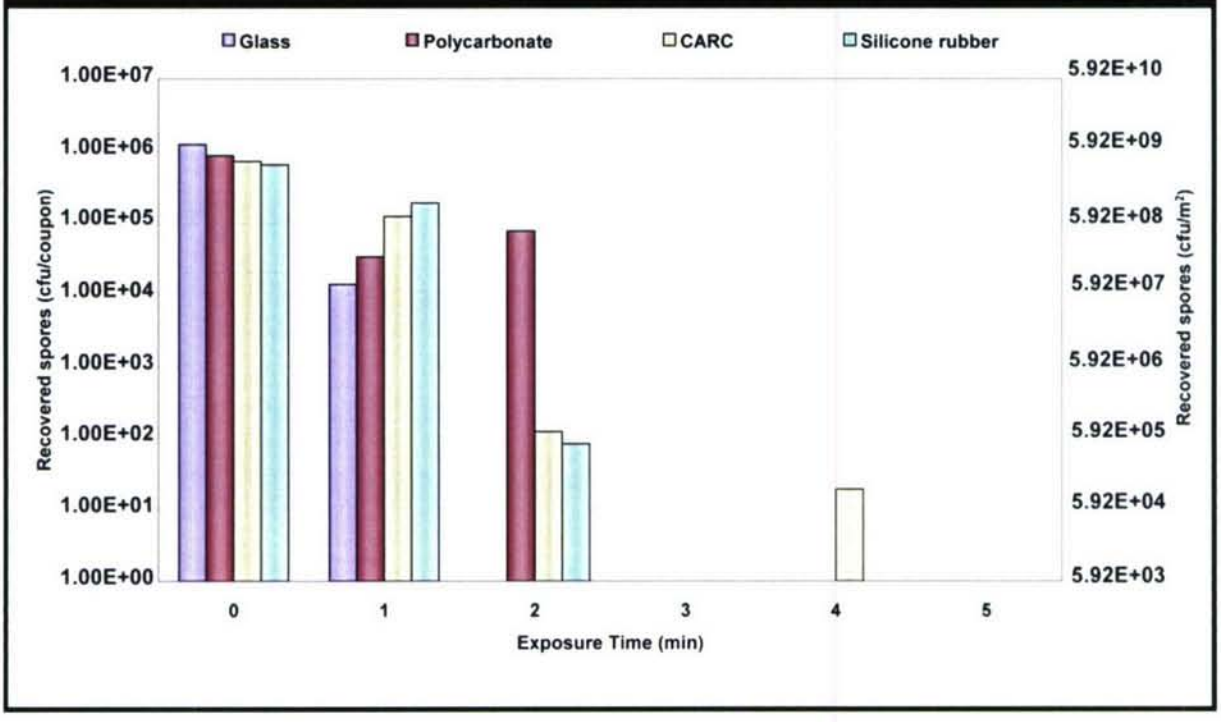
3.4.4 Biological Agent Efficacy Tests

The biological agent efficacy tests were conducted as part of the chambers biological testing and documented.[16] The section from the chambers biological testing report is provided here.

The biological agent efficacy tests utilized contaminated coupons at the same challenge of 1 x 10^6 spores per coupon, which is equivalent to 5.9 x 10^9 cfu/m^2, as the biological surrogate tests. The biological agent efficacy tests are required to demonstrate the effectiveness of fumigant against live agent. The mVHP decontaminant was used. The efficacy test target fumigant concentration was 500-ppm hydrogen peroxide and 30-ppm ammonia.

The *B. anthracis* Ames results showed that for three of the four core materials the six log reduction was achieved within 3-minutes of mVHP exposure. The CARC-coated metal six log reduction was achieved by 5-minutes of mVHP exposure.

Figure 3.4.4: *B. anthracis* Ames Results at Target Fumigant Concentration



The time required to achieve a six-log reduction for *B. anthracis* Ames is far shorter than for *G. stearothermophilus* showing the more conservative nature of *G. stearothermophilus* as an indicator of rendering *B. anthracis* spores nonviable. The results have consistently shown that at 500-ppm hydrogen peroxide and 30-ppm ammonia *G. stearothermophilus* decontamination takes 15 times longer than *B. anthracis* Ames decontamination to achieve the same reduction in viable spores.

3.4.5 Comparison of Coupon Tests to JPID and JSSED ORD Requirements

The JPID ORD specifies a starting challenge of 1×10^8 cfu / m^2. Both ORDs specify the remaining contamination to be less than or equal to 100 cfu / m^2. The ORDs require a 6-log reduction in viable spores to achieve decontamination.

The tests utilized the standard procedures for biological coupon testing. These tests utilize small coupons measuring 1.3 cm by 1.3 cm. When the tests were first started, there was concern that the amount loaded on the coupon was not comparable to the ORD. The standard procedure uses a load of 1×10^6 cfu / coupon. Accounting for coupon area, the initial load is equivalent to 5.9×10^9 cfu / m^2. The challenge used in the standard procedure is greater than what is required.

The existing test method is based on cfu per coupon. The test was conducted to determine if a six log reduction could be achieved with the mVHP technology. The results are presented in terms of log reduction. The 500-ppm hydrogen peroxide and 30-ppm ammonia efficacy tests showed that a 6-log reduction in viable *G. stearothermophilus* spores could be achieved within 30-minutes for most materials, within 60-minutes for all materials. The *B. anthracis* Ames decon tests met the ORD equivalent 6-log reduction in viable spores within 5-minutes of mVHP treatment at 500-ppm hydrogen peroxide and 30-ppm ammonia. The baseline (no fumigant) and low concentration (250-ppm hydrogen peroxide and 15-ppm ammonia) results did not meet the ORD equivalent 6-log reduction which was expected.

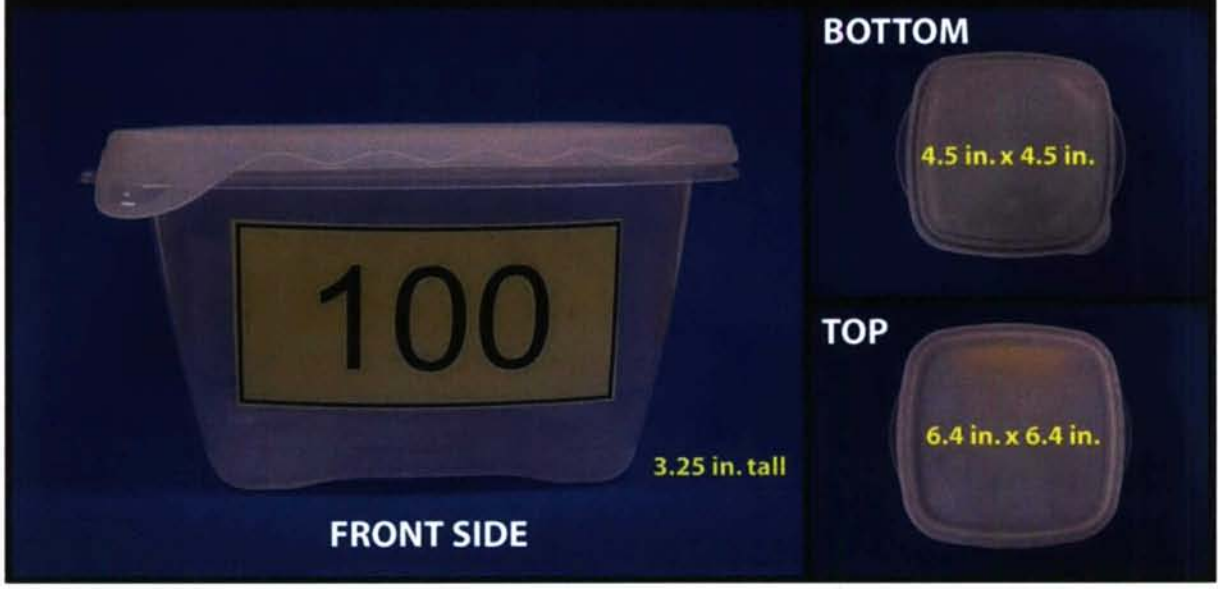
In terms of actual number of spores, the 6-log reduction specified by the JPID ORD is equivalent to the removal of 100,000,000 cfu. The existing test method cannot quantify 100 cfu / m^2 since that is equivalent to 0.017 cfu/coupon. One of the proposed test improvements is to be able quantify the equivalent of 100 cfu / m^2. In terms of absolute numbers, the JPID ORD is equivalent to the removal of 100,000,000 cfu. The 500-ppm hydrogen peroxide / 30-ppm ammonia results show a reduction in spores that is three-orders of magnitude greater than the ORD required reduction. The reduction in spores on silicone, CARC, glass and polycarbonate were on the order of 1,300,000,000; 6,000,000,000; 5,000,000,000; 5,000,000,000; respectively.

3.5 Loading and Spacing Test Results and Discussion

3.5.1 Test Summary

The loading and spacing test matrix was designed to determine the minimum spacing required for the placement of containers representative of the size and shape of hand-held sensitive equipment items. Rubbermaid Take-Along large square containers were used for the spacing test (Figure 3.5.1.1). The Rubbermaid container measurements are 6.4 in^2 at the top, 4.5 in^2 at the bottom, and 3.25 in. tall.

Figure 3.5.1.1: Containers for Representative Size of Sensitive Equipment



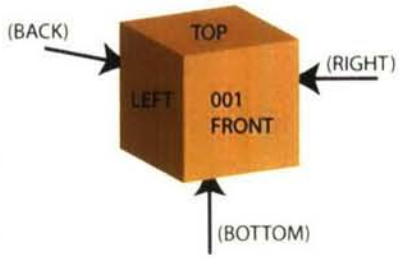
Each container was individually numbered. The number determined the orientations for front, back, top, bottom, left and right. The test matrix was originally designed to begin with 1-inch spacing between containers. Based on the results, the containers would be moved further apart as additional spacing was required. The 1-inch spacing was measured at the upper side of the container just below the lid. Since the containers have arc shaped handles that stick out approximately 0.5 inches, the containers were lined up on the shelves such that the arc shaped handles touched lengthwise down the shelf. Using the shelving as-received, each shelf could hold 60 containers at the 1-inch spacing totaling 300 containers on the rack.

Twenty-six Browne and four Steris hydrogen peroxide chemical indicator strips were used for the early tests; later tests only used the Browne strips. The strips were placed on selected cubes to sample the hydrogen peroxide fumigant distribution throughout the chamber including the corners, by the doors, between articles and between shelves. The placement of the chemical indicator strips for the 1-inch spacing test is shown in Figure 3.5.1.2. Fumigant distribution was determined by monitoring the chemical indicator color change.

Figure 3.5.1.2: 1-Inch Spacing Chemical Indicator Strip Placement

Shelf 1												
Container	001	002	003	004	005	006	007	008	009	010	011	012
CI Location	L											B
Container	013	014	015	016	017	018	019	020	021	022	023	024
CI Location			F									
Container	025	026	027	028	029	030	031	032	033	034	035	036
CI Location			B									
Container	037	038	039	040	041	042	043	044	045	046	047	048
CI Location												
Container	049	050	051	052	053	054	055	056	057	058	059	060
CI Location	F											R
Shelf 2												
Container	061	062	063	064	065	066	067	068	069	070	071	072
CI Location												
Container	073	074	075	076	077	078	079	080	081	082	083	084
CI Location	L											
Container	085	086	087	088	089	090	091	092	093	094	095	096
CI Location				F		M				R	L	
Container	097	098	099	100	101	102	103	104	105	106	107	108
CI Location				B								
Container	109	110	111	112	113	114	115	116	117	118	119	120
CI Location												
Shelf 3												
Container	121	122	123	124	125	126	127	128	129	130	131	132
CI Location												
Container	133	134	135	136	137	138	139	140	141	142	143	144
CI Location										F		
Container	145	146	147	148	149	150	151	152	153	154	155	156
CI Location						T	M			B		
Container	157	158	159	160	161	162	163	164	165	166	167	168
CI Location												
Container	169	170	171	172	173	174	175	176	177	178	179	180
CI Location												
Shelf 4												
Container	181	182	183	184	185	186	187	188	189	190	191	192
CI Location												
Container	193	194	195	196	197	198	199	200	201	202	203	204
CI Location							T					
Container	205	206	207	208	209	210	211	212	213	214	215	216
CI Location			R	L								R
Container	217	218	219	220	221	222	223	224	225	226	227	228
CI Location												
Container	229	230	231	232	233	234	235	236	237	238	239	240
CI Location												
Shelf 5												
Container	241	242	243	244	245	246	247	248	249	250	251	252
CI Location	M											R
Container	253	254	255	256	257	258	259	260	261	262	263	264
CI Location												
Container	265	266	267	268	269	270	271	272	273	274	275	276
CI Location								R	L			
Container	277	278	279	280	281	282	283	284	285	286	287	288
CI Location												
Container	289	290	291	292	293	294	295	296	297	298	299	300
CI Location	L											T

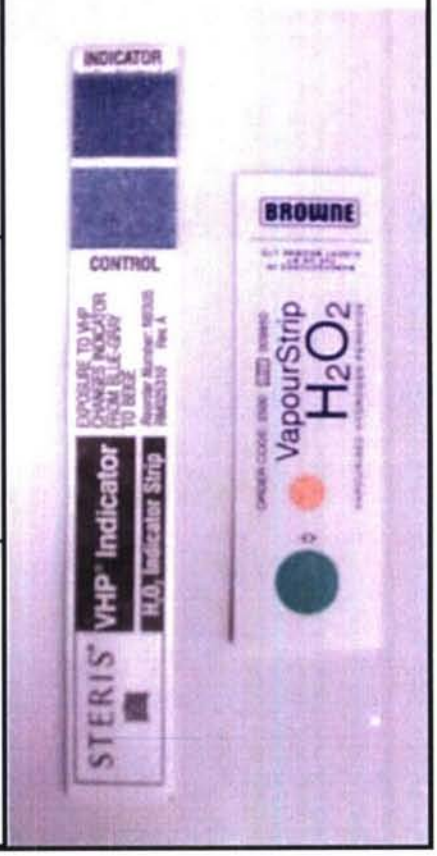
Cube Orientation



Coding

B = Back	F = Front
L = Left	M = Bottom
R = Right	T = Top

Fresh Chem Indicator Strips



In the first test, the hydrogen peroxide concentration was set to 500-ppm for a 60 minute decontamination phase. Ammonia was not used until the last test since the chemical indicator strips were only sensitive to hydrogen peroxide vapor. Ammonia was used in the final test to show that the results were the same with both hydrogen peroxide and ammonia. Six tests were performed to demonstrate the spacing requirement between containers for the SED prototype (Table 3.5.1). The first three tests were conducted at the start of the evaluation and the final three at the end of the SED evaluation after all system modifications were complete.

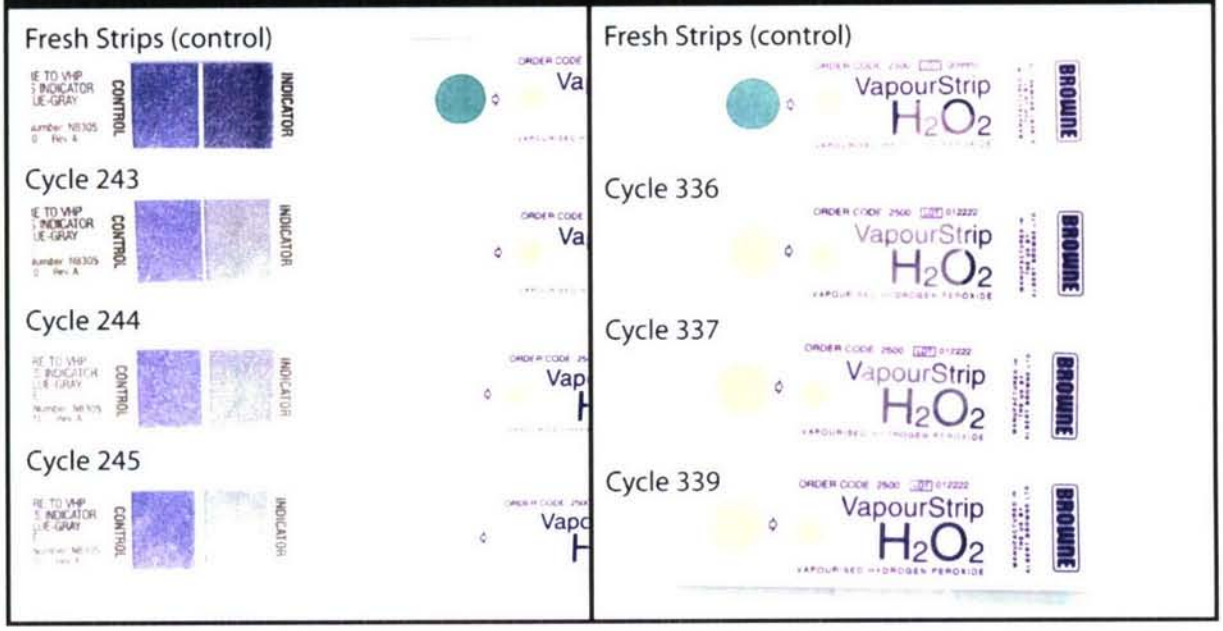
Table 3.5.1: SED Loading Volume Test Matrix

Cycle Number	Decon	Decon Phase Time (min)	Spacing (inches)	Number of Containers	H_2O_2 Concentration (ppm)	NH_3 Concentration (ppm)	Chemical Indicators
243	mVHP	60	1	300	500	0	Browne, Steris
244	mVHP	30	1	300	500	0	Browne, Steris
245	mVHP	30	1	300	750	0	Browne, Steris
336	VHP	60	1	300	500	0	Browne
337	VHP	30	1	300	500	0	Browne
339	mVHP	60	1	300	500	30	Browne

3.5.2 Chemical Indicator Strips

The Browne and Steris chemical indicator strips are both sensitive to hydrogen peroxide; however, the strips differ in observed color and response time when used in the SED box and Lexan replica. The Browne chemical indicator strips turn from green to pink. The Browne strips were determined to be appropriate strips for runs shorter than four hours at 500-ppm hydrogen peroxide. The Steris chemical indicator strips change from blue to beige. The Steris strip color change to beige was not change was not observed in runs shorter than four hours at 500-ppm hydrogen peroxide vapor. The Steris strip color change to beige-yellow was observed at closer to eight hours at 500-ppm hydrogen peroxide vapor. Both indicator brands were used during early studies. The final tests utilized the Browne indicator strips. Representative chemical indicator strips from each run are shown in Figure 3.5.2.

Figure 3.5.2: Loading Test Chemical Indicator Strip Result Samples



3.5.3 Test Results

The 300 containers were numbered and loaded into the SED prototype (Figure 3.8.3.1a). The chemical indicator strips were applied to the appropriate container and side using a single-sided adhesive tape (3.5.3c). The rack was pushed into the decontamination chamber (Figure 3.5.3b). The cycle was performed. After aeration was complete, the chamber was unloaded and the chemical indicator strips were removed and archived. A sample of cube 073 before and after the cycle is shown in Figure 3.5.3d. The strips were visually reviewed and archived. All strips showed a similar color response regardless of position within the decontamination chamber. All strips showed contacting with hydrogen peroxide.

The hydrogen peroxide control charts for dehumidification, conditioning, decontamination and aeration for the tests are provided in Appendix C.

Figure 3.5.3: SED Prototype Loaded with 300 Containers

a) 300 Containers on Prototype Rack

b) Rack Inside Prototype

c) View of Strips between Containers

d) Cycle 245, Container 073 Strips Before and After

3.5.4 Discussion

The Browne and Steris chemical indicator strips were monitored during chambers testing to determine the appropriate chemical indicator for this particular test. The Browne strips were determined the appropriate chemical indicator for short runs.

The chemical indicator strips at the 1-inch spacing test at 500 ppm for a 60-minute decontamination phase showed that proper distribution was achieved. Since the spacing did not need to be increased two additional tests using a shorter decon phase were performed. The 500-ppm and 750-ppm hydrogen peroxide for 30-minute decontamination phase tests also showed that proper distribution was achieved. At the end of the program three additional spacing tests were performed. A test at 500-ppm hydrogen peroxide for both a 60- and 30-minute decontamination phase was conducted to replicate the earlier results. The last test used 500-ppm hydrogen peroxide and 30-ppm ammonia to show the results are the same with ammonia present.

The chamber biological agent surrogate tests showed that a 30-minute decontamination time at 500-ppm hydrogen peroxide and 30-ppm ammonia was needed for the decontamination of the conservative surrogate *G. stearothermophillus*. Whereas, the laboratory work showed that *B. anthracis* Ames spores can be rendered non-viable in a 500-ppm hydrogen peroxide and 30-ppm ammonia vapor within 5-minutes.[16] Using the more conservative biological surrogate values as the biological decontamination time requirement, the SED prototype in the as-received configuration can process 300 contaminated articles in a 30-minute decontamination phase. The total cycle time current is about two hours. With improvements in aeration phase, the total treatment cycle has potential of decontaminating 300 articles in one hour.

The loading test was performed using the equipment rack as-received. The rack consisted of 5-stainless steel shelves spaced at approximately 12-inches apart. Figure 3.5.3b shows that the loading of the 300 containers onto the five shelves does not completely fill the decontamination chamber. If additional shelves were available, it is anticipated that the number of containers could be increased while maintaining fumigant distribution.

3.6 Simulated Sensitive Equipment Exposure Tests

The sensitive equipment exposure tests were conducted to determine the impact of repeated mVHP decontaminant exposures on visual appearance and for some items operational function. The test articles included six DVD players, four radios, four night vision monocular units, five GPS units, one M40 mask and one desktop computer.

3.6.1 Test Summary

The sensitive equipment test articles were divided into three groups control, biological contamination control and test. One DVD player, radio, night vision monocular (NVM) and GPS unit served as control articles. The control articles were not subjected to biological contamination or mVHP exposure. One DVD player, radio, night vision monocular and GPS unit served as biological contamination control articles. The biological contamination control articles were subjected to biological contamination but not mVHP exposure. The biological contamination control articles were used to determine spore recovery efficiency during testing. The biological contamination control samples underwent some mVHP exposure prior to the biological testing, therefore the summary of exposure is included in this section. The test articles underwent the full mVHP exposure tests. Some of the articles were also contaminated with the *G. stearothermophilus* surrogate. The biological equipment efficacy results are discussed in Section 3.7.

The primary test articles (e.g. DVD, NVM, GPS, Radio) were subjected to over 100 hours of mVHP decon-phase time exposure. The M40 mask was subjected to over 100 hours of mVHP decon-phase time exposure. The computer CPU and components were subjected to 43- and 78-hours decon-phase time exposure, respectively. The hours of decon-phase exposure, total cycle time, and cumulative hydrogen peroxide and ammonia CT values are provided in Table 3.6.1.

Table 3.6.1: Equipment Exposure CT Values			
Item	Decon Phase Exposure Time (hr)	Cumulative CT Values (ppm - hr)	
		Hydrogen Peroxide	Ammonia
DVD E02	0	0	0
DVD E03	111	60628	3663
DVD E04	110	59905	3615
DVD E05	110	59905	3615
DVD E06	111	60628	3663
Radio E08	111	60628	3663
Radio E09	111	60628	3663
Radio E10	0	0	0
Night Vision E12	111	60628	3663
Night Vision E13	111	60628	3663
Night Vision E14	0	0	0
GPS E16	111	60628	3663
GPS E17	111	60628	3663
GPS E19	0	0	0
M40 Mask E21	43	24140	1303
PC E20 CPU	43	24140	1303
PC E20 Monitor Keyboard & Mouse	78	42623	2508
0 hr = Contol item			

3.6.2 Test Article Initial Inspection

The test articles were inspected on November 11, 2005. The starting descriptions are provided below. The initial inspection photographs for each item are provided in Appendix B.

DVD Players: Six Polaroid DVD Players, Model PDM-0711, used previously in LOE testing at Eglin AFB, Florida, were used. The items displayed varying degrees of scratching from sand abrasions.

a. DVD E01 (Ser. # B0500010530058755): This item had extensive, though minor, cosmetic scratches on the outside cover. There were still some grains of sand stuck into small spaces, two of the rubber pads on the bottom were missing, and some of the screws holding the case together showed some rusting. Functionally, the DVD player worked to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge.

b. DVD E02 (Ser. # B0500010530058756): This item had extensive, though minor and cosmetic, scratches on the outside cover. The screen appeared to have suffered extensive bubbling and smudging, but on later inspection, this was revealed to be a sacrificial, peel-off plastic protective sheet. When peeled off, the screen was revealed to be in like-new condition. There were still some grains of sand stuck into small spaces, and three of the rubber pads on the bottom were missing. Functionally, the DVD player worked almost to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge. The lid for the DVD did not always latch securely, and even after the STOP button was pushed, the disk often continued to spin.

c. DVD E03 (Ser. # B0500010530058839): This item had minor scratches on the outside cover. There were a few grains of sand stuck into small spaces and one of the rubber pads on the bottom was missing. Functionally, the DVD player worked to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge.

d. DVD E04 (Ser. # B0500010530058840): This item had very minor scratches on the outside cover. Two of the rubber pads on the bottom were missing. Functionally, the DVD player worked to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge.

e. DVD E05 (Ser. # B0500010530072101): This item had almost no scratches on the outside cover. Two of the rubber pads on the bottom were missing. Functionally, the DVD player worked to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge.

f. DVD E06 (Ser. # B0500010530072102): This item had minor, cosmetic scratches on the outside cover. There were still some grains of sand stuck into small spaces, two of the rubber pads on the bottom were missing. There were several fingerprint smudges on the upper left corner of the screen. Functionally, the DVD player worked to specification – it played DVDs, it could advance from scene to scene, the speakers and headphone jack worked, and the batteries, though low, would accept and hold a charge.

Radio Sets, A/N-PRQ-7: Four non-functional A/N-PRQ-7 radios were received.

a. Radio E07 (Ser. # F/N 016): This radio appeared to be in excellent condition. All buttons responded as expected, and there was no evidence of any physical damage. The lamination on the rear dataplate was smooth and even. Battery contacts were clean and bright, with no signs of corrosion.

b. Radio E08 (Ser. # F/N 028): This radio appeared to be in very good condition. All buttons responded as expected, and there was no evidence of any physical damage except for a small scratch on the middle of the display screen. The lamination on the rear dataplate was smooth and even. Battery contacts were clean and bright, with no signs of corrosion.

c. Radio E09 (Ser. # F/N 110): This radio appeared to be in excellent condition. All buttons responded as expected, and there was no evidence of any physical damage. The lamination on the rear dataplate was smooth and even. Battery contacts were clean and bright, with no signs of corrosion.

d. Radio E10 (Ser. # F/N 034): This radio appeared to be in excellent condition. All buttons responded as expected, and there was no evidence of any physical damage. The lamination on the rear dataplate was smooth and even. Battery contacts were clean and bright, with no signs of corrosion.

Night Vision Monocular Units (NVM): Four Night Vision Monocular Units tested were Yukon CE Model NV-MT2 24022, 3 x 42-power, made in Russia. All four items showed evidence of wear on the raised portions of the unit, such as the front outside edges of the IR emitter, the battery cap, and the bulges in the unit body for the battery case and IR emitter. Some still had sand trapped in small crevices, and two were missing the labels with the model information.

a. NVM E11 (Ser. # 30062513): This unit worked to specification. It showed cosmetic scratches and wear on the raised points. About ¾ of the name plate was missing upon the initial inspection.

b. NVM E12 (Ser. # 30062504): This unit worked to specification. It showed cosmetic scratches and wear on the raised points. The lenses were a bit dirty, with some fingerprint smudges.

c. NVM E13 (Ser. # 30061774): This unit worked to specification. It showed cosmetic scratches and wear on the raised points. The brand label was missing upon initial inspection.

d. NVM E14 (Ser. # 30061824): This unit worked to specification. It showed cosmetic scratches and wear on the raised points.

Global Positioning System (GPS): The five GPS units provided for testing were all Garmin Rino 120 models. Two were provided with Eveready Industrial AA batteries, three with commercial grade AA batteries. All five units were able to track satellites and navigate to specification and receive radio transmissions, but only the radios with the Industrial grade batteries were able to transmit radio signals. When the batteries were switched between radios, the capability to transmit moved with the industrial grade batteries. We are at a loss to explain the difference.

a. GPS E15 (Ser. # 41539078): The unit appeared to be almost new. There were some grains of fine sand stuck in small crevices, and some minor abrasions of the green coating on the plastic body at the bottom. The unit functioned to specification.

b. GPS E16 (Ser. # 41545485): The unit appeared to be almost new. There were some grains of fine sand stuck in small crevices, and some minor abrasions of the green coating on the plastic body at the bottom. The unit functioned to specification.

c. GPS E17 (Ser. # 41539076): The unit appeared to be almost new. There were some grains of fine sand stuck in small crevices, and some minor abrasions of the green coating on the plastic body at the bottom. The unit functioned to specification.

d. GPS E18 (Ser. # 41542362): The unit appeared to be almost new. There were some grains of fine sand stuck in small crevices, and some minor abrasions of the green coating on the plastic body at the bottom. The unit functioned to specification.

e. GPS E19 (Ser. # 41545506): The unit appeared to be almost new. There were some grains of fine sand stuck in small crevices, and some minor abrasions of the green coating on the plastic body at the bottom. The unit functioned to specification.

Personal Computer (PC): The PC used in this test had been previously been exposed to the fumigant mixture during testing on the fumigation of the interior of a C-141 Starlifter aircraft

at Davis-Monthan AFB, Arizona. During shipping, the PC was dropped, resulting in some minor damage to the hard-drive, which was repaired before the PC went back into the chamber. The monitor, keyboard, and mouse were all used in the C141 testing, and worked fine.

CB Protective Respirator, M40 series, with C2 Filter Canister: A production test model of the M40 protective mask was provided by RDECOM for exposure in the JSSED chamber. The mask was supplied with a prototype second skin facepiece, new elastic head harness, and an expired C2 filter canister, but without a hood or eyelens outserts. The mask was fully functional, and functioned to specification (though the C2 canister had expired, and was thus unusable in a toxic environment). Neither the silicone rubber of the facepiece, nor the butyl rubber second skin showed any evidence of oxidation or dry rot. There was a small scratch in the anodization of the retaining ring for the right eyelens.

3.6.3 Test Article Final Inspection

The test article final inspection summary was on March 1st, 2006. The final inspection descriptions are provided below. The final inspection photographs for each item are provided in Appendix B.

DVD Players: The six DVD players tested in the prototype JSSEDS unit were all Polaroid DVD Players, Model PDM-0711. They had all been used previously in LOE testing at Eglin AFB, Florida, and displayed varying degrees of scratching from sand abrasions, especially on the outside covers.

a. DVD E01 (Ser. # B0500010530058755): This unit was used for very limited exposure to the mVHP process. It was contaminated with bio surrogate *G. stearothermophilus* for the first trial – a one-hour run – and then was uncontaminated for the remaining 22 hours of exposure. It remained fully functional, with no physical or performance changes noted after a total of 23 hours exposure to mVHP (total Concentration x time [CT] value of 12716 ppm-hr of hydrogen peroxide, and 812.0 ppm-hr of ammonia). After the end of the test, the unit was connected to a battery charger overnight, and the battery showed no evidence of any effects from the fumigation process – it remained fully functional and held the charge.

The only change noticed at the end of the trial period was that some of the small, anodized screws holding the case together appeared to have lost part of their anodization – the color has changed from a dark black to a dark brown. What appeared to have been corrosion at the beginning of the test appears to have been chips in the anodization, as there is no evidence of corrosion at the end.

b. DVD E02 (Ser. # B0500010530058756): This unit was never used in the chamber. Upon initial inspection, the screen appeared to be already damaged – but it turned out to be a peel-off plastic coating that we missed during the pre-inspection. Since it was never in the chamber, it became a control item. As such, there were no changes to the system – everything remained fully functional, and there were no cosmetic changes noted. During the final inspection, we finally realized that the bubbled screen was, in fact, the peel-off protective layer and removed it.

c. DVD E03 (Ser. # B0500010530058839): This unit was exposed to a total of 110.5 hours of mVHP – a total CT of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia. After 81.5 hours exposure (44954.6 ppm-hr of peroxide, 2731.9 ppm-hr of ammonia), we noticed the first bubbles appear on the DVD screen. The seven bubbles formed were relatively small – none larger than 1cm in diameter – and were discrete.

Unsure about how these bubbles got started or formed, we decided to run a side experiment – we deliberately made a small puncture and a scratch in the upper right quadrant of the screen, away from any bubbles that had already

formed. This intentional damage was contained inside a yellow grease pencil box drawn on the screen. After each subsequent trial, the existing bubbles grew larger and coalesced, and new ones formed – but none formed where the screen had been deliberately damaged.

At no time, however, did these bubbles alter the functionality of the DVD player. While unsightly, even at their largest the bubbles had no effect on the visibility of the movies (unless one desired to watch the film with the screen at an extreme oblique angle).

Functionally, the DVD player worked to specification. The battery contacts, even after 110.5 hours in a highly oxidizing atmosphere, showed no corrosion whatsoever. Electrical wiring inside the player was all clean and bright, the laser lens was clear, and everything worked to specification. The anodization on the exposed faces of the screws holding the case together had been burned off, which might lead to subsequent corrosion, but no rusting was evident at the final inspection. The electrical contacts for the headphones and the AC power worked well, and the battery accepted and maintained a charge.

d. DVD E04 (Ser. # B0500010530058840): This unit was exposed to a total of 109.5 hours of mVHP – a total CT of 59904.8 ppm-hr of peroxide, 3615.3 ppm-hr of ammonia. Except for the removal of the anodization on the screws, there was no evidence of any physical damage whatsoever. Functionally, the DVD player was unchanged from its pre-test capabilities. The battery contacts showed no corrosion whatsoever. Electrical wiring inside the player was all clean and bright, the laser lens was clear, and everything worked to specification. The electrical contacts for the headphones and the AC power worked well, and the battery accepted and maintained a charge.

e. DVD E05 (Ser. # B0500010530072101): This unit was exposed to a total of 109.5 hours of mVHP – a total CT of 59904.8 ppm-hr of peroxide, 3615.3 ppm-hr of ammonia. Except for the removal of the anodization on the screws, there was no evidence of any physical damage whatsoever. The battery contacts showed no corrosion whatsoever. Electrical wiring inside the player was all clean and bright and the laser lens was clear. The electrical contacts for the headphones and the AC power worked well, and the battery accepted and maintained a charge.

Functionally, this DVD player was the only one that showed any effects from the testing. After 101.5 hours of exposure to mVHP (55646.5 ppm-hr of peroxide, 3326.5 ppm-hr of ammonia), the spin speed of the disk in the player seemed to be unusually high – when running, the player palpably vibrated from the high speed of the disk – and the player had trouble loading the video. A sharp rap on the left side of the case seemed to be enough to jog it into loading, but then it had trouble advancing – perhaps there is a problem with the motor

control moving the laser beam. Further examination by an electronics expert may reveal the problem.

f. DVD E06 (Ser. # B0500010530072102): This unit was exposed to a total of 110.5 hours of mVHP – a total CT of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia. Except for the removal of the anodization on the screws, there was no evidence of any physical damage whatsoever. The battery contacts showed no corrosion whatsoever. Electrical wiring inside the player was all clean and bright, the laser lens was clear, and everything worked to specification. The electrical contacts for the headphones and the AC power worked well, and the battery accepted and maintained a charge.

Radios: The four A/N PRQ-7 radios were delivered to the test group with dead batteries. After repeated attempts to get replacement batteries so we could perform function tests on the radios, we were informed that we would not be issued any, as the asset manager was afraid that we would inadvertently push the wrong button, thus sending out a distress signal that would summon SWAT teams to the test site. Therefore, only physical observations can be recorded.

a. Radio E07 (Ser. # F/N 016): This item was contaminated with *G. stearothermophilus* for the first trial (1 hour, 723.6 ppm-hr of peroxide, 47.7 ppm-hr of ammonia), and then underwent a further 22 hours of testing without contamination (total exposure: 23 hours, 12716.1 ppm-hrs peroxide, 812.0 ppm-hrs ammonia). By the end of the 23 hours exposure, some small bubbles had formed underneath the plastic laminate over the data plate on the back of the radio. Electrical contacts for the radio and the battery were clean and bright.

b. Radio E08 (Ser. # F/N 028): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). After 23 hours exposure, the data plate lamination began to show some bubbling. The bubbles grew and coalesced upon further exposure to mVHP, but the laminate over the data plate never detached or became separated from the radio, and all the information on the data plate was easily readable. Electrical contacts for the radio and the battery were clean and bright.

c. Radio E09 (Ser. # F/N 110): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). After 23 hours exposure, the data plate lamination began to show some bubbling. The bubbles grew and coalesced upon further exposure to mVHP, but the laminate over the data plate never detached or became separated from the radio, and all the information on the data plate was easily readable. Electrical contacts for the radio and the battery were clean and bright.

After 69.5 hours of exposure, the test team noticed some grey-white powdery residue near the vent hole in the main battery – it appears to be some by-

product from the deterioration of the dead battery itself. The residue did not change shape, color, or size with subsequent exposure to mVHP.

d. Radio E10 (Ser. # F/N 034): This test item was never exposed to mVHP. There were no changes observed.

Night Vision Monoculars (NVM): The four Night Vision Monoculars tested were Yukon CE Model NV-MT2 24022, 3 x 42-power, made in Russia. All four items showed evidence of wear on the raised portions of the unit, such as the front outside edges of the IR emitter, the battery cap, and the bulges in the unit body for the battery case and IR emitter. Some still had sand trapped in small crevices, and two were missing the labels with the model information.

a. NVM E11 (Ser. # 30062513): This item was exposed to mVHP for 23 hours (total CTs of 12716.1 ppm-hrs peroxide, 812.0 ppm-hrs ammonia). With the exception of a fingerprint on the objective lens, there were no physical changes noted. The unit worked to specification at all times. The item was delivered to us with about ¾ of the brand label missing, but there were no further changes.

b. NVM E12 (Ser. # 30062504): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). With the exception of a fingerprint smudge and some marker residue on the objective lens, there were no physical changes noted. The unit worked to specification at all times.

c. NVM E13 (Ser. # 30061774): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). With the exception of a fingerprint smudge and some marker residue on the objective lens, the only physical change noted was the appearance of some small patches of a gummy residue on the rubber cowling around the objective lens. This material rubbed off easily, and there was no evidence of any physical change to the rubber underneath. The unit worked to specification at all times.

d. NVM E14 (Ser. # 30061824): This item was never exposed to mVHP. No physical changes were noted at any time. The unit worked to specification at all times.

Global Positioning System (GPS): The five GPS units provided for testing were all Garmin Rino 120 models. Two were provided with Eveready Industrial AA batteries, three with commercial grade Eveready AA batteries. All five units were able to track satellites and navigate to specification and receive radio transmissions, but only the radios with the Industrial grade batteries were able to transmit radio signals. When the batteries were switched between radios, the capability to transmit moved with the industrial grade batteries. We are at a loss to explain the difference.

a. GPS E15 (Ser. # 41539078): This item was exposed to mVHP for 23 hours (total CTs of 12716.1 ppm-hrs peroxide, 812.0 ppm-hrs ammonia). There were no physical or functional changes noted at any time.

b. GPS E16 (Ser. # 41545485): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). There were no physical or functional changes noted at any time.

c. GPS E17 (Ser. # 41539076): This item was exposed to mVHP for 110.5 hours (total CTs of 60628.4 ppm-hr of peroxide, 3663.0 ppm-hr of ammonia). There were no physical or functional changes noted at any time.

d. GPS E18 (Ser. # 41542362): This unit was exposed to mVHP for 109.5 hours (total CTs of 59904.8 ppm-hr of peroxide, 3615.3 ppm-hr of ammonia). There were no physical or functional changes noted at any time.

e. GPS E19 (Ser. # 41545506): This item was never exposed to mVHP. No physical changes were noted at any time. The unit worked to specification at all times.

Personal Computer (PC): The PC components were exposed to varying amounts of mVHP: the CPU unit was exposed to 43 hours of mVHP (CTs of 24140.3 ppm-hr of peroxide and 1302.5 ppm-hr of ammonia), while the keyboard, mouse, and monitor were exposed to mVHP for 78 hours (CTs of 42623.1 ppm-hr of peroxide, 2508.0 ppm-hr of ammonia). The CPU experienced a lower CT due to the efforts made to recover the damage to the hard drive caused by rough handling. Once the software was restored on the damaged hard drive, the computer functioned quite normally, although a bit more slowly than before due to using different hard drive sectors. None of the other components showed any physical or functional changes whatsoever.

CB Protective Respirator, M40 series, with C2 Filter Canister: The protective mask was exposed to mVHP for 43 hours (CTs of 24140.3 ppm-hr of peroxide and 1302.5 ppm-hr of ammonia). None of the polymeric components of the mask – silicone rubber facepiece, butyl rubber second skin, butyl rubber outlet valve cover, polycarbonate eyelenses, or the elasticized head harness – showed any effects at all from exposure to mVHP. The only damage noted was to the anodized metal components of the mask.

We first noticed the destruction of the anodizing after about 14 hours of mVHP exposure (CTs of 8466.5 ppm-hr of peroxide, 371.4 ppm-hr of ammonia) – it was first evident on the eyelens retaining rings and the filter canister. As mVHP exposure increased, more and more of the anodization burned off the metal parts on the mask. After 14 hours, it was noticeable on the filter canister and eyelens rings. After 19 hours, we noticed that the drink-tube coupler was affected (except for a small patch covered by the rubber storage tube on the outlet valve cover), the anodizing on the head harness buckles was disappearing, the anodizing on the eyelens retaining rings was almost gone, the filter had developed a speckled appearance, and that some of the anodization was burning off the front voicemitter retaining ring. After 27

hours exposure, all of the anodized parts were beginning to discolor and bleach out. After 35 hours, the anodizing on both the front voicemitter (interior and exterior surfaces) and side voicemitter (exterior surfaces only) was completely gone, the front voicemitter retaining ring was patchy, and the side voicemitter retaining ring was discoloring. By the completion of 43 hours exposure, all of the anodized metal parts showed bleaching and removal of anodizing to varying degrees except the interior face of the side voicemitter.

3.6.4 Equipment Findings and Discussion

Fourteen articles were subjected to 40 or more hours of mVHP decon-phase exposure. Cosmetic effects related to adhesive peeling were observed on radio labels and DVD screen anti-glare coating coatings. Only one DVD player showed delamination (i.e. bubbling) during testing. Although no immediate effects were observed, there was a slower prolonged delamination of the other DVD player screens. The screen that delaminated more quickly may have had a scratch or imperfection in the anti-glare coating enabling hydrogen peroxide to penetrate more quickly. Cosmetic discoloration of anodized metal on the M40 mask was observed. All of the electronics remained functional after testing. The PC, which was not functioning well at the start of testing, displayed booting problems; however, those problems cannot be tied to this testing. The test by test observations are detailed in the following subsections.

3.6.4.1 M40-Series Military Mask

An M40-series protective mask was placed into the SED box for exposure trials starting with Cycle 310, Equipment Test 3.1 on 15 February 2006. Following this first 80-min decontamination cycle, no changes were observed. Later that day, a second test, Equipment Test 5.1, was conducted, and ran overnight. Following this 740-min decontamination cycle, the test team noted that the anodizing was disappearing from the exposed metal surfaces of the filter canister. After further exposures, the test team noted that the anodizing on the voicemitter retaining ring, drink tube coupler, and eye lens retaining ring was visually disappearing, and the anodizing on the filter canister was continuing to degrade. After further exposures, the test team observed that the anodizing was burning off all the exposed metal surfaces, inside and outside the mask face piece – eye lens retainers, drink tube coupler, voicemitter retainers (front and side), voicemitters, and the head harness buckles. By the end of the testing, the mask had been exposed to enough peroxide to render the anodized metal to a bright, shiny silver-grey, which could be a field safety hazard. Clear indications of these changes are depicted by comparing Figure 3.6.4.1a to Figure 3.6.4.1g. Figure 3.6.4.1e compares a mask with no exposure to mVHP to one following 24 hours of exposure: note the marked bleaching on the eye lens retaining ring. None of the damage observed affected the function of the mask; however the damages to the anodizing would render the mask non-tactical. The mask underwent 43 hours of cumulative decontamination time and a total CT of 24140 ppm-hr peroxide and 1303 ppm-hr ammonia. Based on current treatment concentrations and chemical agent efficacy data, it is not anticipated that a mask would be subjected to a long enough cycle to turn the mask shiny (i.e. all annodization removed); however, some loss in color would be anticipated.

3.6.4.2 DVD Player Visual Observations

DVD E01: DVD E01 was inserted into the SED box for testing starting with Cycle 304, Equipment Test 1.1, on 8 February 2006. After 23 hours of exposure, no changes were observed. (Figure 3.6.4.2.2) DVD E01 underwent a total CT of 12716 ppm-hr peroxide and 812 ppm-hr ammonia.

DVD E03: DVD E03 was inserted into the SED box for testing starting with Cycle 304, Equipment Test 1.1, on 8 February 2006. Following Equipment Test 5.3 on 22 February 2006 (a cumulative exposure of 81.5 hours), seven bubbles were noticed on the screen. These

were the result of a de-lamination of one or more of the layers of polymer on the screen, but while cosmetically displeasing, the bubbles did not effect the operation of the DVD player. Following another exposure, the test team observed that the bubbles had grown larger. At this point, the test director suggested that DVD E03 be deliberately damaged in a previously unaffected area to see if the bubbling could be correlated to a puncture or scratch or some other flaw in the lamination. The test team first drew small (approximately 1.5 cm square) boxes on the upper right-hand corner of the screen with a grease pencil. A small scratch and a puncture were made inside these boxes. Despite several more trials, no bubbling was ever observed in the areas of deliberate damage – however, the pre-existing bubbles continued to grow and coalesce. Figures 3.6.4.2.1 E03a – E03d depict the growth and addition of new bubbles throughout testing. 3.6.4.2.1 E03a was taken during the initial inspection, 3.6.4.2.1 E03b was following Equipment Test 5.3, 3.6.4.2.1 E03c was following Equipment Test 4.2 on 22 February 2006, and 3.6.4.2.1 E03d was final inspection photo on 28 February 2006. DVD E03 underwent 111 hours of exposure and a total CT of 60628 ppm-hr peroxide and 3663 ppm-hr ammonia.

DVD E04: DVD E04 was inserted into the SED box for testing starting with Cycle 304, Equipment Test 1.1, on 8 February 2006. After 110 hours of exposure, no immediate effects were observed. The test director suggested that the items should be stored and monitored for a few months after the end of the exposure testing. During a follow-up inspection one week later, the test team observed two small bubbles that had appeared on the screen. Once started, these bubbles grew slightly larger, as observed in subsequent follow-on inspections. DVD E04 underwent a total CT of 59905 ppm-hr peroxide and 3615 ppm-hr ammonia. Figure 3.6.4.2.1 E04a was taken during the initial inspection, 3.6.4.2.1 E04b was taken during the final inspection, and 3.6.4.2.1 E04c was taken during the first post-trial storage inspection.

DVD E05: DVD E05 was inserted into the SED box for testing starting with Cycle 304, Equipment Test 1.1, on 8 February 2006. After 110 hours of exposure, no immediate effects were observed. Re-examination one week later unveiled two small bubbles appearing on the screen. DVD E05 underwent a total CT of 59905 ppm-hr peroxide and 3615 ppm-hr ammonia. Figure 3.6.4.2.1 E05a was taken during the initial inspection, Figure 3.6.4.2.1 E05b was taken during the final equipment inspection, and Figure 3.6.4.2.1 E05c was taken at the first post-trial storage inspection.

DVD E06: DVD E06 was inserted into the SED box for testing starting with Cycle 304, Equipment Test 1.1, on 8 February 2006. After 111 hours of exposure, no effects were observed. DVD E06 underwent a total CT of 60628 ppm-hr peroxide and 3663 ppm-hr ammonia.

Figure 3.6.4.1: M40 Mask mVHP Exposure History - Visual Inspection

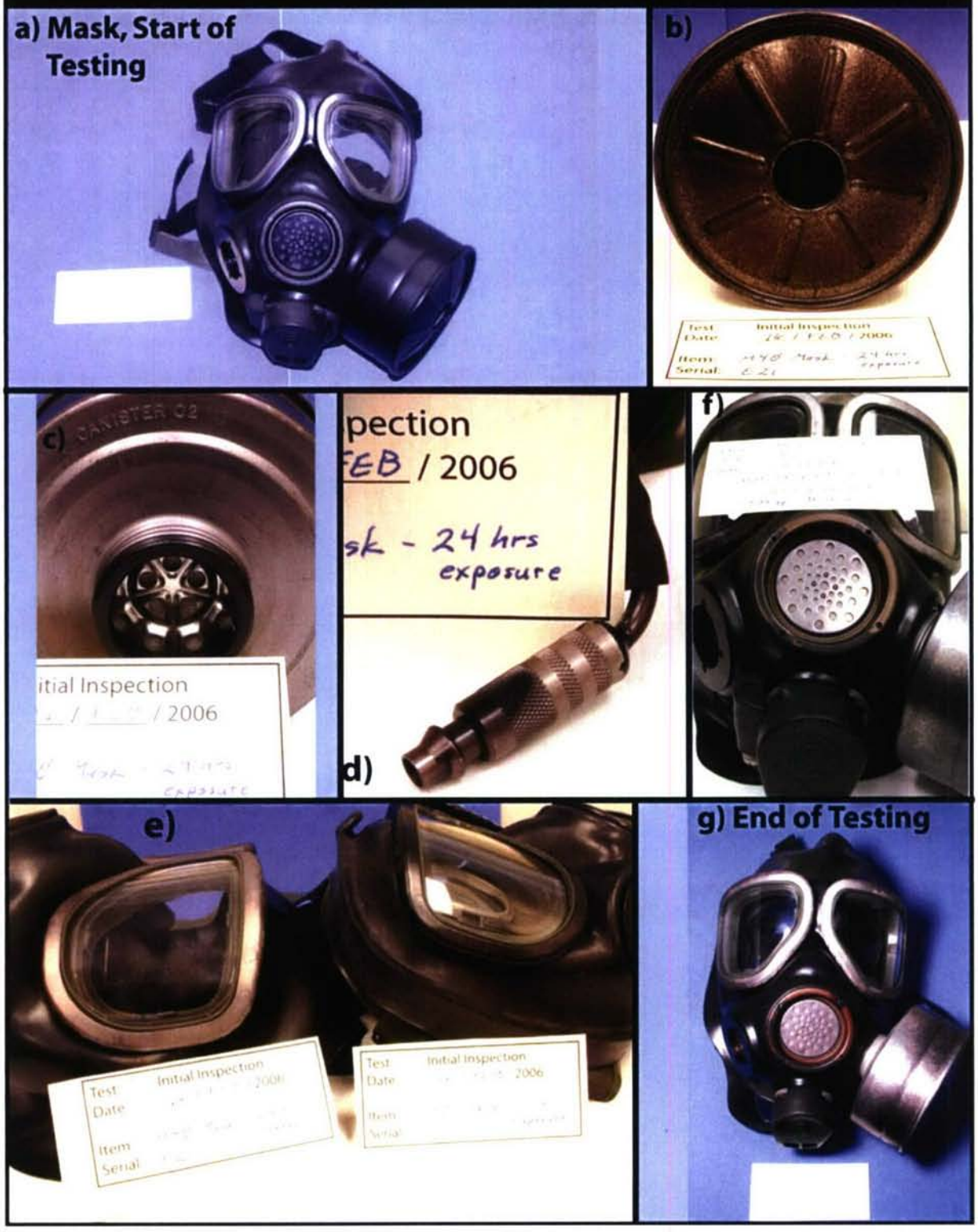
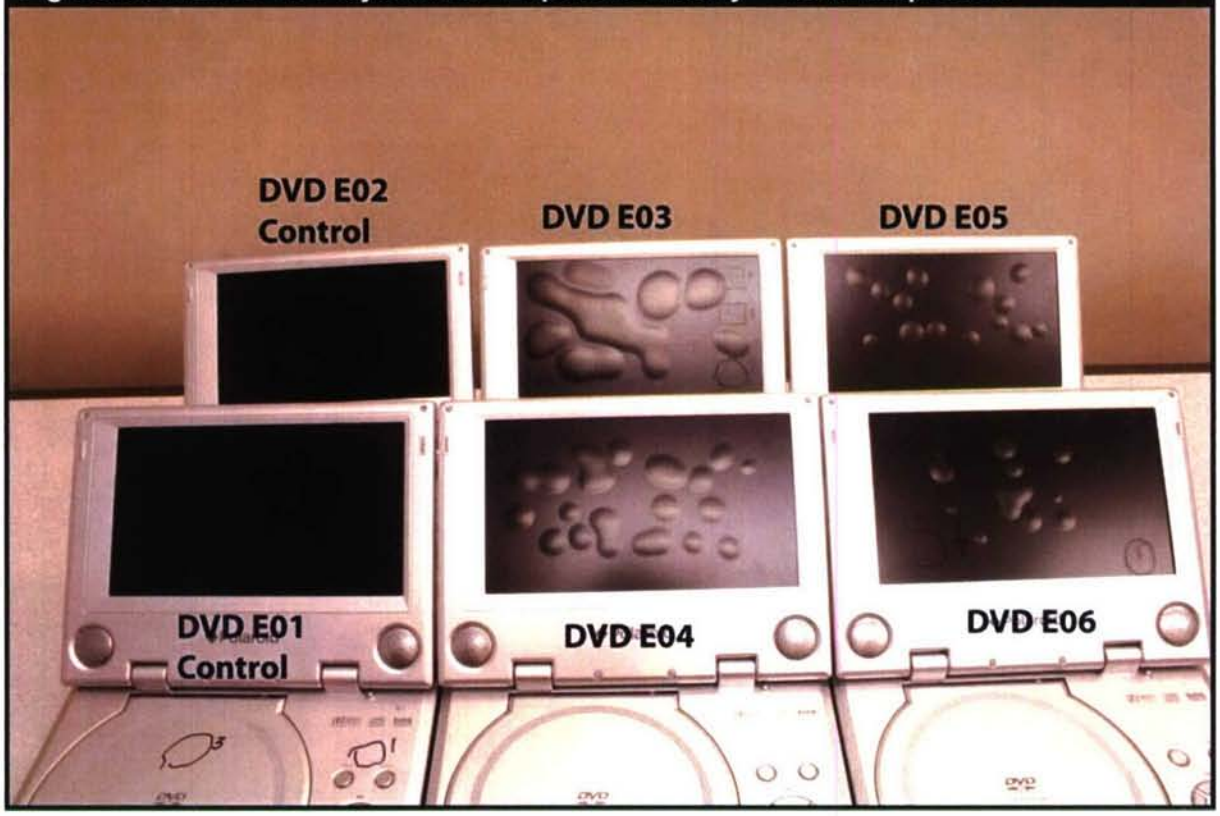


Figure 3.6.4.2.1: DVD Player mVHP Exposure History - Visual Inspection

Figure 3.6.4.2.2: DVD Player mVHP Exposure History - Visual Inspection



3.6.4.3 Radio Visual Observations

Radio E07: Beginning with cycle 304, Equipment Test 1.1, on 8 February 2006, Radio E07 was inserted into the SED box. After 23 hours of exposure, no effects were observed. After 32 hours of exposure bubbling was observed on the back label. Radio E07 underwent 32 hours of exposure and a total CT of 12716 ppm-hr peroxide and 812 ppm-hr ammonia. Figure 3.6.4.3.1-E07a was initial photo, 3.6.4.3.1-E07b was final inspection.

Radio E08: Beginning with cycle 304, Equipment Test 1.1, on 8 February 2006, Radio E07 was inserted into the SED box. After 23 hours of exposure, no effects were observed. After 32 hours of exposure bubbling was observed on the back label. Radio E08 underwent 111 hours of exposure and a total CT of 60628 ppm-hr peroxide and 3663 ppm-hr ammonia. Figure 3.6.4.3.2-E08a was initial photo, 3.6.4.3.2-E08b was final inspection.

Radio E09: Beginning with cycle 304, Equipment Test 1.1, on 8 February 2006, Radio E07 was inserted into the SED box. After 23 hours of exposure, no effects were observed. After 32 hours of exposure bubbling was observed on the back label. Radio E09 underwent 111 hours of exposure and a total CT of 60628 ppm-hr peroxide and 3663 ppm-hr ammonia. Figure 3.6.4.3.3-E09a was initial photo and 3.6.4.3.3-E09b was final inspection.

Figure 3.6.4.3.1: Radio mVHP Exposure History - Visual Inspection

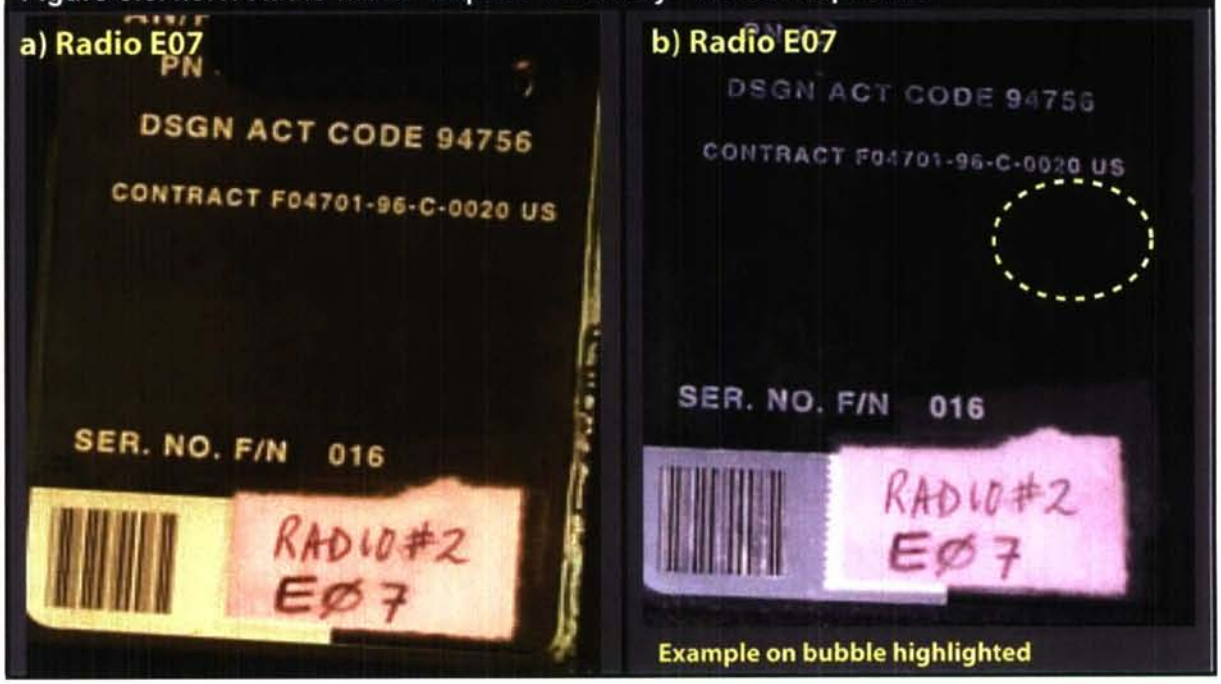


Figure 3.6.4.3.2: Radio mVHP Exposure History - Visual Inspection

a) Radio E08

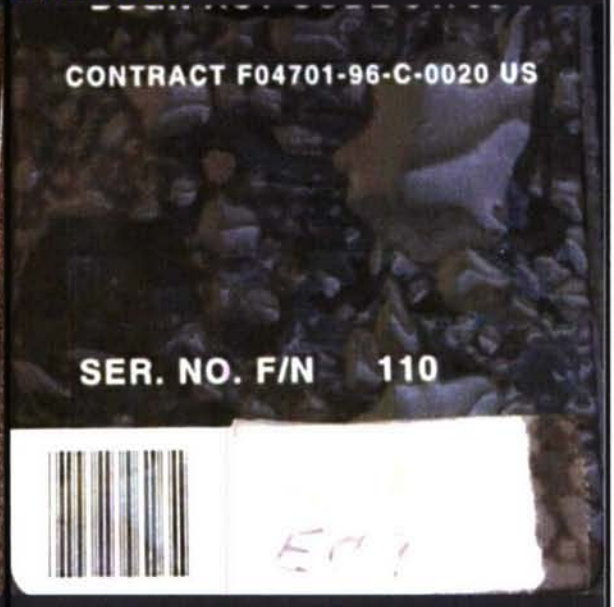
b) Radio E08

Example on bubble highlighted

Figure 3.6.4.3.3: Radio mVHP Exposure History - Visual Inspection

a) Radio E09

b) Radio E09



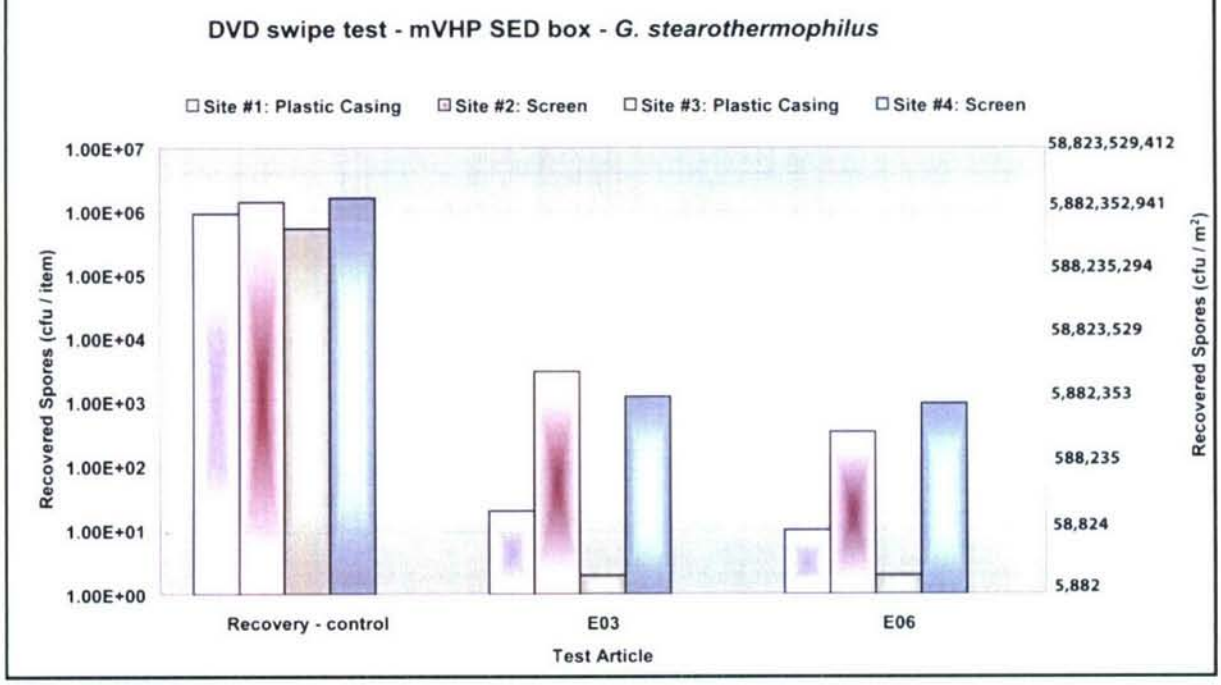
3.7 Biological Surrogate Contaminated Simulated Sensitive Equipment Tests

The simulated sensitive equipment efficacy tests utilized biological surrogate contamination on different areas of the equipment. The coupon challenge was 1 x 10^6 spores per dosing area (i.e. area about size of the bio coupons) which is equivalent to 5.9 x 10^9 cfu/m^2. The mVHP decontaminant was used. The efficacy test target fumigant concentration was 500-ppm hydrogen peroxide and 30-ppm ammonia. The sample collection times were based on the chambers efficacy results for the coupon samples. The biological surrogate contaminated simulated sensitive equipment tests were cycles 304, 318, 320 and 322. A 60-minute decon phase was to be used for all four tests. Run 318 decon phase parameter was mistyped resulting in an 80-minute decon phase. Each data point below was one replicate.

3.7.1 Simulated Sensitive Equipment Test Results: DVD Players

The DVD players were a mix of several types of materials and textures: textured coated glass and smooth plastic casing. The DVD plastic casings displayed a greater than 5-log reduction in *G. stearothermophilus* spores. The performance was similar to the results for other nonporous surfaces such as polycarbonate and glass. The DVD screens displayed a 2- to 3-log reduction in *G. stearothermophilus* spores. The screen areas took longer to decontaminate than the glass coupons. The glass coupons showed a complete 6-log reduction after the 30-minute decon phase test. The difference can be attributed to the types of coatings common to handheld electronic screens. Most screens will have some form of anti-scratch or anti-glare coatings. These coatings typically have some porosity associated with them which makes it different than plain glass.

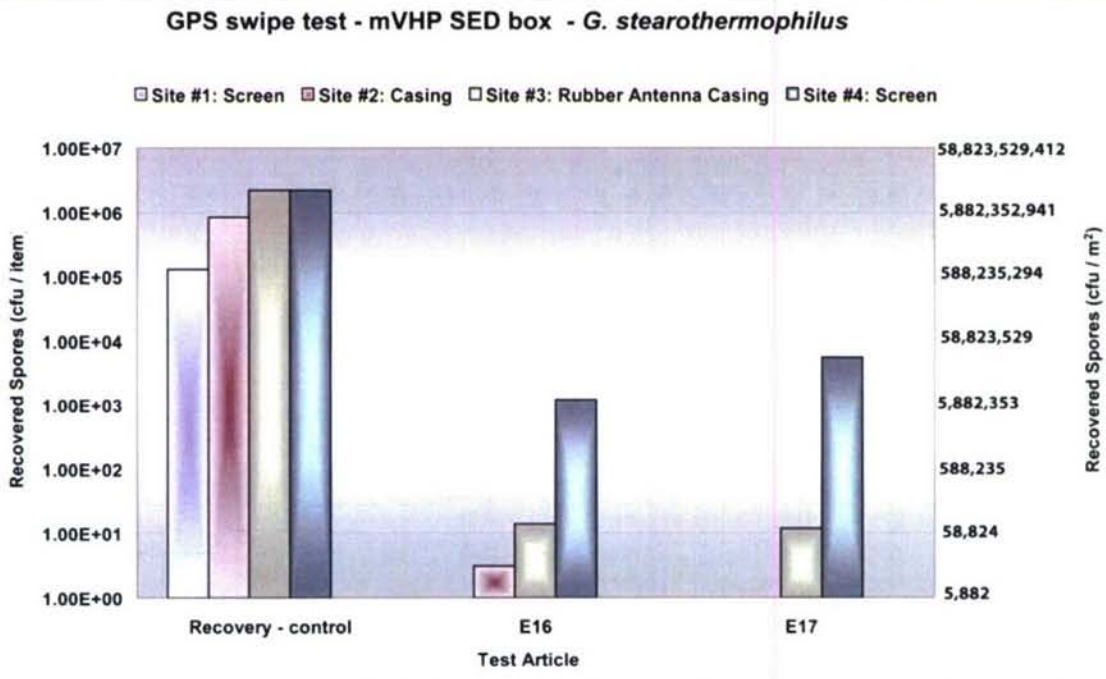
Figure 3.7.1: SED Box Equipment Test Results - DVD Players



3.7.2 Simulated Sensitive Equipment Test Results: GPS Units

The GPS units were a mix of several types of materials and textures: smooth glass, rubber casing, and textured plastic casing. The GPS unit screen was a smooth surface compared to the DVD players. The difference in texture resulted in a difference in decontamination efficacy. The GPS screen samples showed a 5- to 6-log reduction in viable spores. The soft rubber antenna casing showed only a 1- to 3-log reduction in viable spores (Figure 3.7.2).

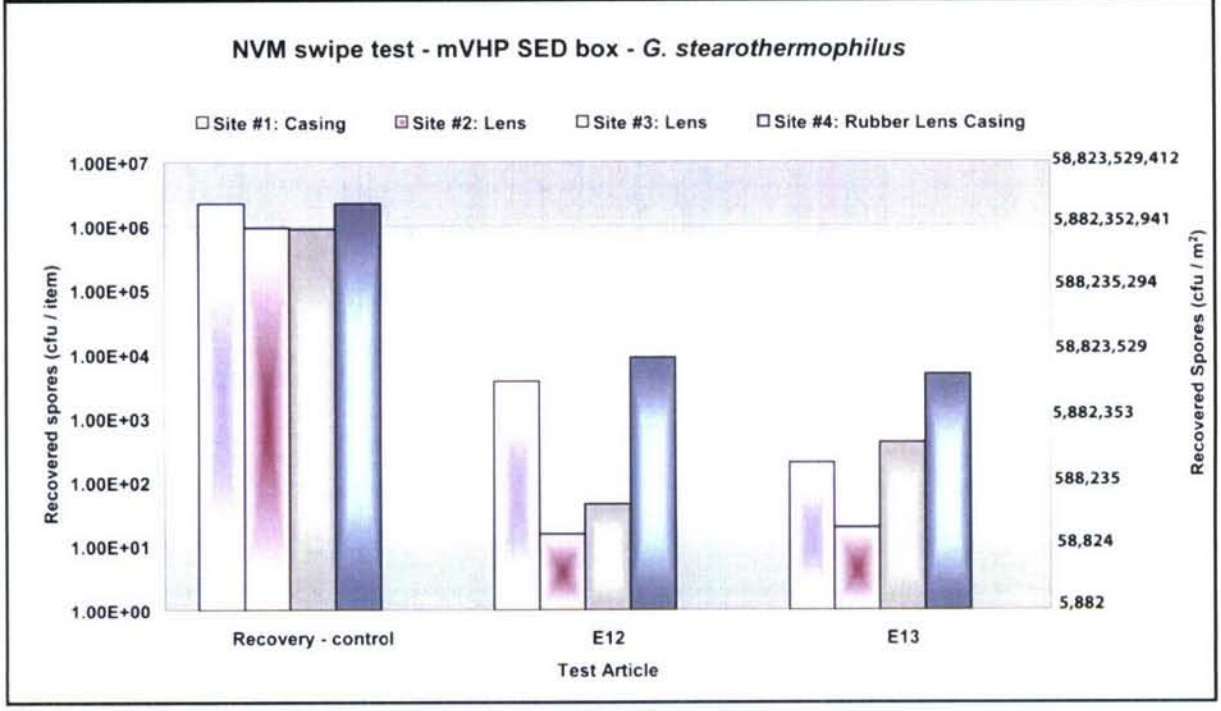
Figure 3.7.2: SED Box Equipment Test Results - GPS Units



3.7.3 Simulated Sensitive Equipment Test Results: NVM Units

The NVM units were a mix of several types of materials and textures: smooth lens glass, rubber lens casing, and textured plastic casing. The rubber casing showed about a 2-log reduction in viable spores. The textured plastic casing showed a 2.5- to 4-log reduction in viable spores. The smooth lens glass had the largest reduction of viable spores at 3- to 5-log.

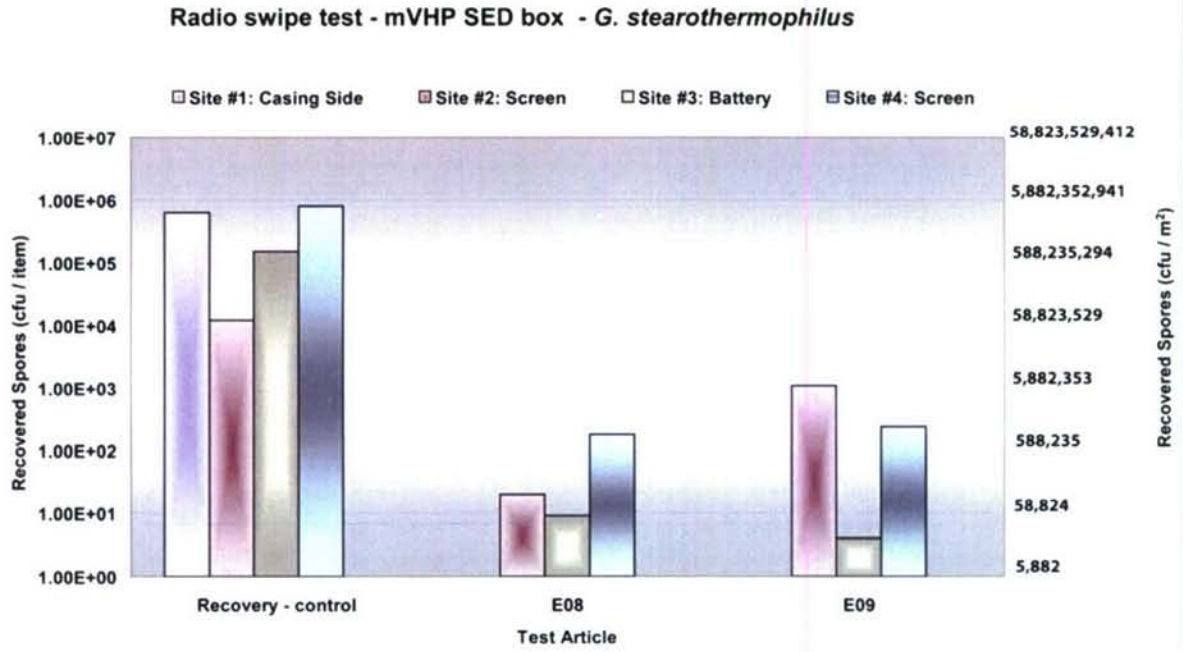
Figure 3.7.3: SED Box Equipment Test Results - NVM Units



3.7.4 Simulated Sensitive Equipment Test Results: Radios

The radios were a mix of several types of materials and textures: hard plastic casing with labels, a glass screen, rubberized buttons. The hard casing showed a 5- to 6-log reduction in viable spores. The screen showed a 3- to 5-log reduction in viable spores (Figure 3.7.4). The larger spread in the screen results is attributed to wiping the small screen area.

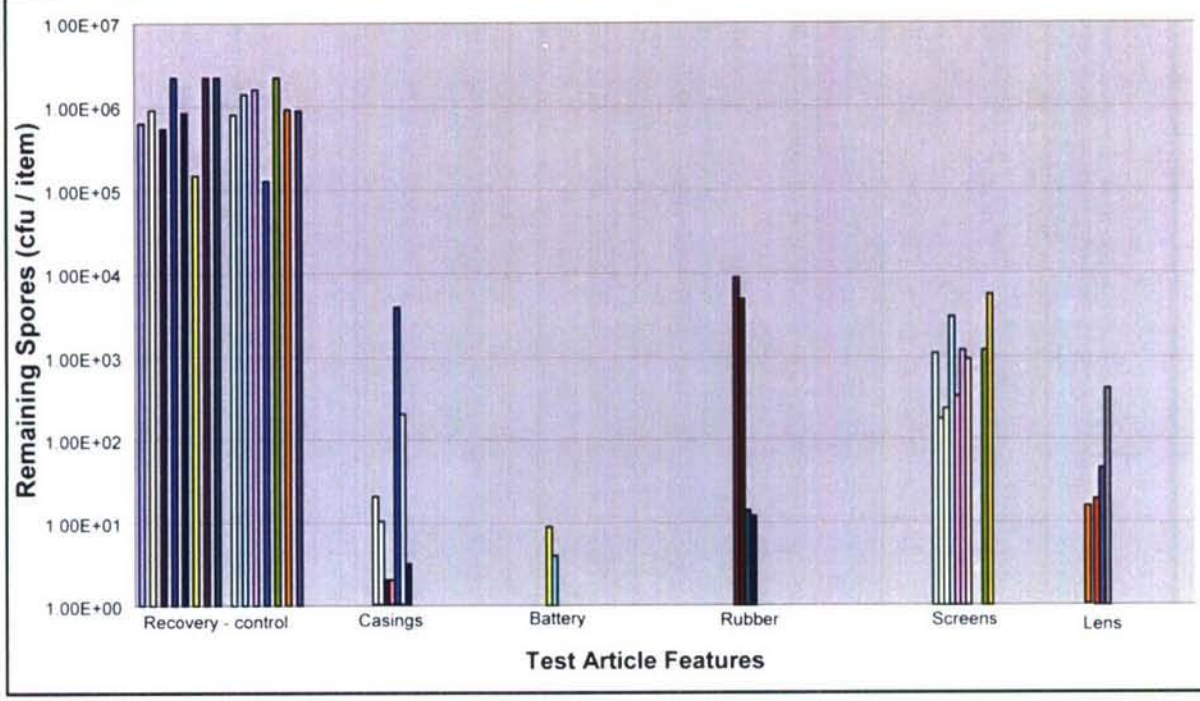
Figure 3.7.4: SED Box Equipment Test Results - Radios



3.7.5 Discussion

The purpose of this test was to show the applicability of the mVHP SED prototype for electronics. The focus of the testing was on electronic post-treatment operability and visual appearance and prototype loading density. The procedures for testing on actual electronics are as not as well developed as the coupon testing. Real items are composites of materials types and textures. The handling and sampling of test articles is not well developed. These biological contamination tests were not done with statistical replicates for analysis; however, the tests provided early insight into key material during optimization stage. These tests were also run using the same time-points as the coupon tests. Tests were not run for longer duration to determine efficacy time due to time constraints with personnel and the upcoming C141 field trial. These results still provide value.

Figure 3.7.5: SED Box Equipment Test Results - Material Classes



The anti-scratch / anti-glare coatings on glass screens and soft rubber materials pose the greatest decontamination challenge. This result is not novel, porous materials are often the harder materials to clean.

The JPID ORD specifies a starting challenge of 1×10^8 cfu / m^2. Both ORDs specify the remaining contamination to be less than or equal to 100 cfu / m^2. The ORDs require a 6-log reduction in viable spores to achieve thorough decontamination. In terms of actual number of spores, the 6-log reduction specified by the JPID ORD is equivalent to the removal of 100,000,000 cfu. All of the articles showed a removal of at least 100,000,000 cfu. During system optimization studies, item test methods should be developed and validated to enable similar studies as done with coupons.

3.8 SED Prototype Cycle Time

The mVHP decontamination process is a 4-phase process. The time to complete each phase is for the runs conducted during this evaluation are provided in Table 3.8. The prototype was able to rapidly dehumidify and condition the interior space to the treatment concentration. The decon phase is dependent on the type of contamination. The time to aerate was the most variable step ranging from a few minutes to three hours. With optimization, a biological cycle could be as short as 60 to 120 minutes in this prototype.

Table 3.8: SED Prototype Cycle Time

Cycle #	Dehumidify Time, min.	Conditioning Time, min.	Decon Phase Time, min.	Aeration Time, min.
315	5	5	50	43
337	5	3	50	420*
304	7	4	80	21
320	34	75*	80	60
306	7	4	80	61
336	34	16	80	78
322	7	4	80	131
339	6	7	80	146
318	7	7	110	46
305	5	3	200	50
310	3	3	200	68
332	7	5	320	79
324	6	3	350	10
330	4	3	350	20
335	7	5	500	60
308	5	3	500	63
319	6	4	500	70
311	5	2	500	72
333	7	5	500	77
334	7	4	500	342*
331	1	2	740	78
323	6	4	740	92
321	5	4	740	179
Average	**8**	**5**	**-----**	**72**
St Dev	**8**	**3**	**-----**	**40**
%	**103**	**63**	**-----**	**56**

*** Denotes outlier value**

3.9 Hydrogen Peroxide Consumption

The mVHP decontamination process is a 4-phase process. The hydrogen peroxide is injected during both the conditioning and decon phases. The SED prototype used a flowrate of 20 cfm. The SED prototype used approximately 140- to 170-grams of hydrogen peroxide per hour (Table 3.9). Run 309 showed an unusually high consumption, this was not understood. The Lexan box had a 40 cfm flowrate and the consumptions were essentially doubled. Assuming that the G. stearothermophilus reaction with hydrogen peroxide is first order, the higher flower rate resulted in a shorter spore halflife. The balance of flowrate and consumption is an area for future system optimization.

Table 3.9: SED Prototype Hydrogen Consumption

Date	Run ID	H2O2 Target (ppm)	Total Peroxide Consumed (gm)	Injection Duration (min)	Total Peroxide Consumed (gm/hr)	Peroxide Consumed (Decon only) (gm)	Decon Duration (min)	Peroxide Consumed (Decon only) (gm/hr)	Comments
1/27/2006	285	500	258.3	84	184.5	222.5	80	166.9	Tented Decon Chamber, no cart
1/27/2006	291	500	257.9	86	179.9	218.4	80	163.8	Tented Decon Chamber, no cart
1/27/2006	292	500	234.5	83	169.5	211.8	80	158.9	Tented Decon Chamber, no cart
2/28/2006	337	500	173.0	53	195.8	144.9	50	173.9	300 - 6x6-inch cubes on Metal Rack
2/28/2006	336	500	399.7	96	249.8	238.3	80	178.8	300 - 6x6-inch cubes on Metal Rack
3/1/2006	339	500	478.1	87	329.7	411.2	80	308.4	300 - 6x6-inch cubes on Metal Rack
2/8/2006	304	500	251.6	84	179.7	214.5	80	160.9	Equipment contaminated with G. Stearo
2/15/2006	320	500	428.1	155	165.7	203.7	80	152.8	Equipment contaminated with G. Stearo
2/16/2006	322	500	246.8	84	176.3	207.4	80	155.5	Equipment contaminated with G. Stearo
2/14/2006	318	500	343.3	117	176.1	295.0	110	160.9	Equipment contaminated with G. Stearo
2/13/2006	315	500	169.6	55	185.0	135.8	50	163.0	G. Stearothermophilus coupons
2/9/2006	306	500	240.1	84	171.5	200.9	80	150.7	G. Stearothermophilus coupons
2/8/2006	305	500	532.7	203	157.5	502.9	200	150.9	Uncontaminated equipment
2/10/2006	310	500	511.3	203	151.1	484.3	200	145.3	Uncontaminated equipment
2/22/2006	332	500	856.8	325	158.2	815.6	320	152.9	Uncontaminated equipment
2/17/2006	324	500	896.4	353	152.4	873.4	350	149.7	Uncontaminated equipment
2/21/2006	330	500	898.9	353	152.8	872.2	350	149.5	Uncontaminated equipment
2/9/2006	308	500	1259.1	503	150.2	1231.1	500	147.7	Uncontaminated equipment
2/10/2006	311	500	1251.7	502	149.6	1234.6	500	148.2	Uncontaminated equipment
2/14/2006	319	500	1361.9	504	162.1	1211.0	500	145.3	Uncontaminated equipment
2/23/2006	333	500	1289.7	505	153.2	1249.0	500	149.9	Uncontaminated equipment
2/24/2006	334	500	1324.9	504	157.7	1290.6	500	154.9	Uncontaminated equipment
2/27/2006	335	500	1293.9	505	153.7	1252.7	500	150.3	Uncontaminated equipment
2/15/2006	321	500	1825.2	744	147.2	1791.6	740	145.3	Uncontaminated equipment
2/16/2006	323	500	1819.4	744	146.7	1788.2	740	145.0	Uncontaminated equipment
2/21/2006	331	500	2006.3	742	162.2	1988.3	740	161.2	Uncontaminated equipment

3.10 SED Prototype Initial Engineering Tests

The Steris SED prototype was received at ECBC for evaluation. The SED prototype was not tested prior to the ECBC testing. The chamber Lexan replica was constructed to enable live agent testing under environmental engineering controls without sacrificing the actual prototype. The Lexan box was an identical mVHP system in distribution (i.e. inlet, outlet and fan placement), sensor placement, operation temperature range, operation humidity range and fumigant concentration. The only difference between the units that was discovered during the SED engineering tests was that the carbon filter was too small and limited the unit flowrate. The two units differed in flowrate. The chamber unit operated at 40 cfm and the SED box at 20 cfm.

The Lexan replica enabled rapid identification of typical prototype "issues" by having a second venue to compare performance. The SED prototype was initially unable to render spores non-viable in a similar period of time as the Lexan replica. Comparing flowrates and peroxide consumption, the SED prototype has an increased demand for hydrogen peroxide, despite having a lower flowrate. The increased demand immediately flagged a material of construction compatibility problem. Construction materials can have different degrees of demand and decomposition capability for vaporous decontaminants. The high consumption indicated such a problem. In order to continue with the project testing, the interior walls were lined with plastic and the metal cart removed for the biological and equipment studies (Figure 3.10). The cart was only used for the loading study. A recommendation for future systems is a material demand study similar to one completed as part of an EPA partnership focused on building interior materials.[17]

Test Summary Notes from the Initial Engineering Tests

During the early trials, the SED Prototype system had difficulty achieving and maintaining the target concentrations of peroxide inside the exposure chamber, as determined by the peroxide and ammonia sensors. In many trials, despite the sensors reading concentrations that should have been sufficient to completely bleach the Steris Peroxide test strips, the test strips showed little or no color change. The chamber had to work for a considerable time to achieve a peroxide concentration of 250 ppm, struggled for 500, had great difficulty reaching 750 ppm, and was completely incapable of reaching and maintaining 1000 ppm.

A number of modifications were tested in an attempt to pinpoint the source of the problem. The first course of action was verification of sensors; sensors were operational. Several configurations of sensor placement were tested; the inlet and outlets were switched; the exhaust system was modified to incorporate a larger gas particulate filter unit (GPFU); and the test chamber was heavily weather-stripped and sealed to prevent intake air from the doors (system is maintained at slight negative pressure), yet the problem persisted.

Data being analyzed from a completely independent peroxide test indicated that certain metals have a catalytic effect on the peroxide, breaking it down rapidly and reducing the effective concentration in the immediate vicinity. This led the test team to theorize that the materials used to construct the inside walls of the exposure chamber and the sample rack may, in fact, be the source of the problem.

To test this new hypothesis, the test team decided to replace the metal sample cart with a plastic shelving unit, and to "tent" the inside surfaces with polyethylene sheeting in an effort to reduce the consumption of peroxide. A large roll of polyethylene sheeting was purchased from a local hardware store, along with chemical resistant duct tape, and this was used to completely cover the interior walls, ceiling, and floor, and the inside surfaces of the access doors. Holes were punched through the plastic to permit the inlet and outlet, fans, and sensor blocks free access to the interior of the test chamber. Figure 3.10 illustrates the SED box wall modification.

Once the entire chamber interior had been covered, the test team ran several engineering test runs to see if the modifications were effective. Peroxide consumption rates, as measured by the pumping rates, dropped dramatically, and the chamber was able to easily maintain 500 ppm, and could readily achieve 1000 ppm.

Figure 3.10: Plastic-Lined Interior and Shelving Unit

3.11 Validation of SED Prototype to Lexan Replica

Chamber and SED prototype fumigant tests were conducted at two different concentrations: 250-ppm hydrogen peroxide (H_2O_2) with 15-ppm ammonia (NH_3) [hereafter abbreviated as 250/15], and 500-ppm H_2O_2 with 30-ppm NH_3 [500/30].

The first comparison of the data for each concentration is between the temporal response and the concentration-time (CT) value, respectively, of the two chambers with respect to their efficacy on the four coupon materials. The purpose of this evaluation is to show that the results obtained between the Chamber and SED prototype are comparable, thus validating the Chamber Lexan replica as representative of the mVHP SED prototype.

3.11.1 Low-Concentration Comparison

The time-based efficacy results for 250/15 against the biological surrogate *G. stearothermophilus* are provided in Figure 3.11.1a. The differing sample access methods of the two test chambers makes it difficult to remove coupons at precisely matching exposure times and CTs. The Chamber system was accessible at user-selectable intervals for withdrawal of sample coupons at pre-designated exposures; whereas, the SED prototype needed to run the full four-phase cycle before samples could be removed for analysis. While the individual sets of data cannot be compared directly from here, it is evident that the peroxide is destroying the contaminant. The data was then compared in terms of CT which was calculated by integrating the concentration of peroxide over the decontamination time period (Figure 3.11.1b).

Based on CT, the 80-minute SED samples were exposed to almost the identical CT value as the 60-minute chamber samples. The CT value for the SED prototype samples was 251 ppm-hr of peroxide, and the chamber CT value was 258 ppm-hr (a difference of 2.6%). Each chamber had one data point that could have been rejected as an outlier, but was retained due to the small sample size. The Student's t-test compared the results for identical coupon materials from the two chambers. The t-test results are unable to reject the hypothesis at the $p = 0.1$ significance level that the data from the two chambers was statistically identical. Within the limits of the sample size, no statistically significant difference in the performance of the SED prototype and the Chambers test box can be detected under these test conditions.

Assuming that the fumigation/decontamination is a 1st order process, exponential trend lines were calculated for the various data sets that compare the different rates of destruction of the biological surrogate for the two test chambers. The exponential fits and corresponding half-life ($t_{½}$) values for *G. stearothermophilus* are listed in Table 3.11.1. From the available data, it appears that the half-life of *G. stearothermophilus* on the various test coupons in the SED prototype is comparable to that of the surrogate coupons in the Lexan chamber test box under the test conditions. This further reinforces the premise that the two chambers are functioning in a comparable manner.

Table 3.11.1: Low-Concentration Half-Life						
Coupon Material	SED Prototype			Lexan Box		
	Equation	R^2	t½ (min)	Equation	R^2	t½ (min)
CARC-painted	y = 5.7×105e-0.004x	1.00	173	y = 6.5×105e-0.006x	0.9	126
Glass	y = 6.6×105e-0.012x	1.00	58	y = 2.0×106e -0.014x	0.86	50
Polycarbonate	y = 6.6×105e-0.005x	1.00	136	y = 1.0×106e-0.015x	0.92	46
Silicone	y = 7.3×105e-0.026x	1.00	27	y = 6.5×105e-0.003x	0.97	231

3.11.2 Target-Concentration Comparison

The time-based efficacy results for 500/30 against the biological surrogate *G. stearothermophilus* are provided in Figure 3.11.2a. The low- concentration test had significant contamination remaining on all the coupons after two hours (only 1- to 3-logs killed); whereas, the target-concentration test spore concentration was reduced to below the minimum detection limit (MDL) within 90 minutes (5- to 6-logs killed). Only the CARC-painted coupon has any surviving spores after 50 minutes of exposure, while in most cases all the spores are destroyed within 30 minutes. The 500/30 concentration exposure is significantly more effective at destroying *G. stearothermophilus* spores on the four coupon surfaces than the 250/15 setting. Figure 3.11.2b compares the CT response of the systems. Again, CARC-painted aluminum appears to be slightly more difficult to decontaminate than other materials.

In this case, there are no data sets that are directly comparable with regards to the CT value as there were for the 250/15 trials. The Chamber Lexan box appears to be rendering the *G. stearothermophilus* non-viable more rapidly than the SED prototype under the 500/30 fumigation conditions. Table 3.11.2 presents the exponential fit for the different rates of destruction of the biological surrogate for the two test chambers, along with the respective half-lives.

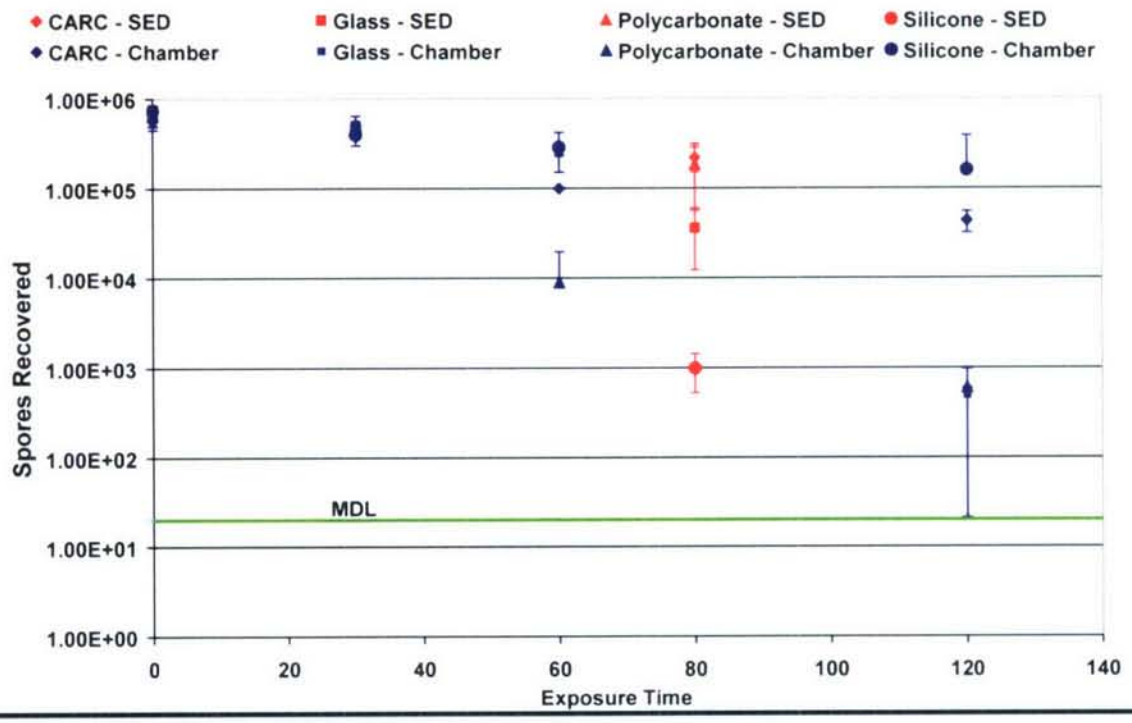
Table 3.11.2: Target-Concentration Half-Life						
Coupon Material	SED Prototype			Lexan Box		
	Equation	R^2	t½ (min)	Equation	R^2	t½ (min)
CARC-painted	y = 6.6×105e-0.015x	0.96	46	y = 5.6×105e-0.023x	1.00	30
Glass	y = 4.1×105e-0.015x	0.88	46	y = 6.6×105e-0.039x	1.00	18
Polycarbonate	y = 3.7×105e -0.015x	0.88	46	y = 6.6×105e-0.039x	1.00	18
Silicone	y = 1.1×105e -0.013x	0.88	53	y = 7.3×105e-0.039x	1.00	18

3.11.3 Summary

From this data, *G. stearothermophilus* in the SED prototype has about twice the half-life of *G. stearothermophilus* in the Lexan box at the 500/30 conditions. The two units only differed in operational flow rate, the SED unit was limited by the exhaust filter to 20 cfm; whereas, chamber flow was 40 cfm. Within the experimental limits of our tests, and taking into account the different materials of construction and variations, such as flowrate, the SED prototype and the Lexan test chamber appear to provide comparable results.

Figure 3.11.1: Low-Concentration Comparison

a) Plot in Terms of Time



b) Plot in Terms of CT

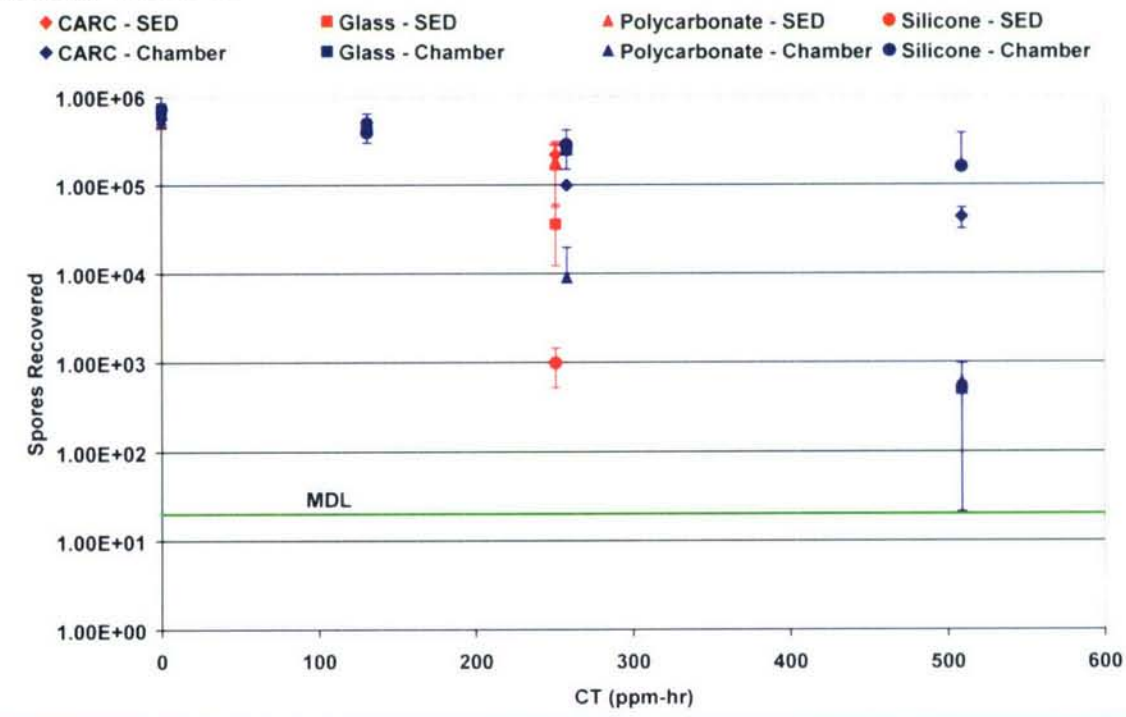
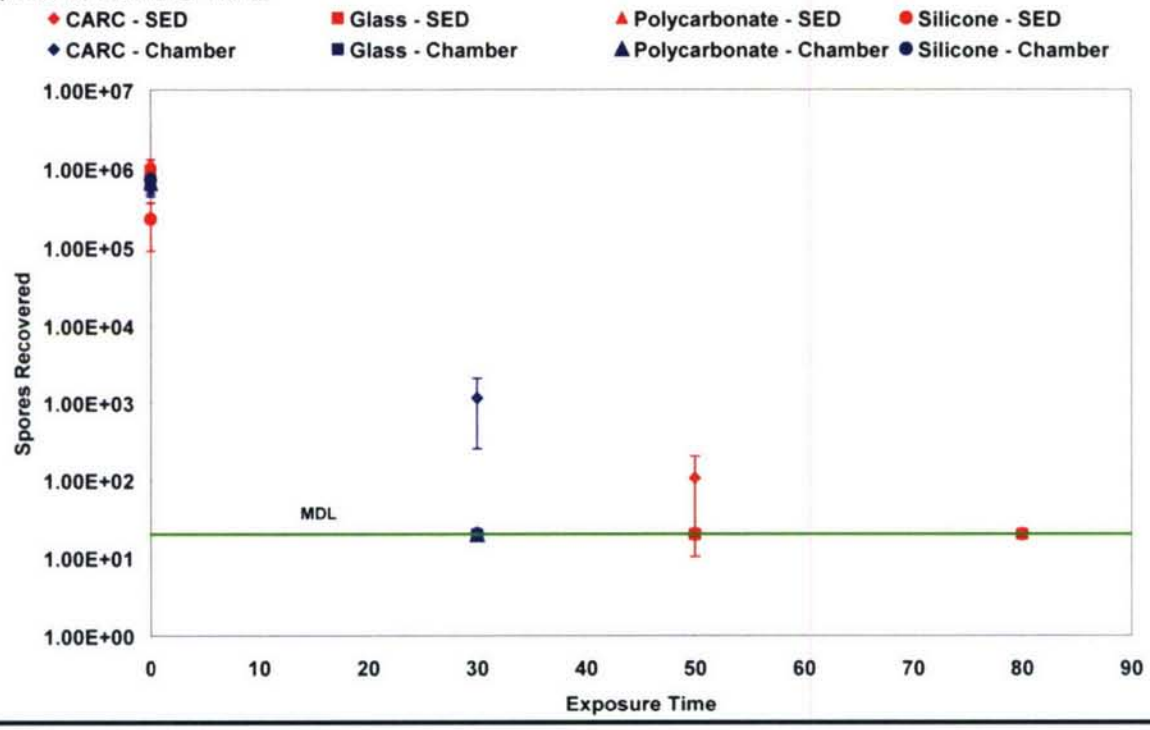
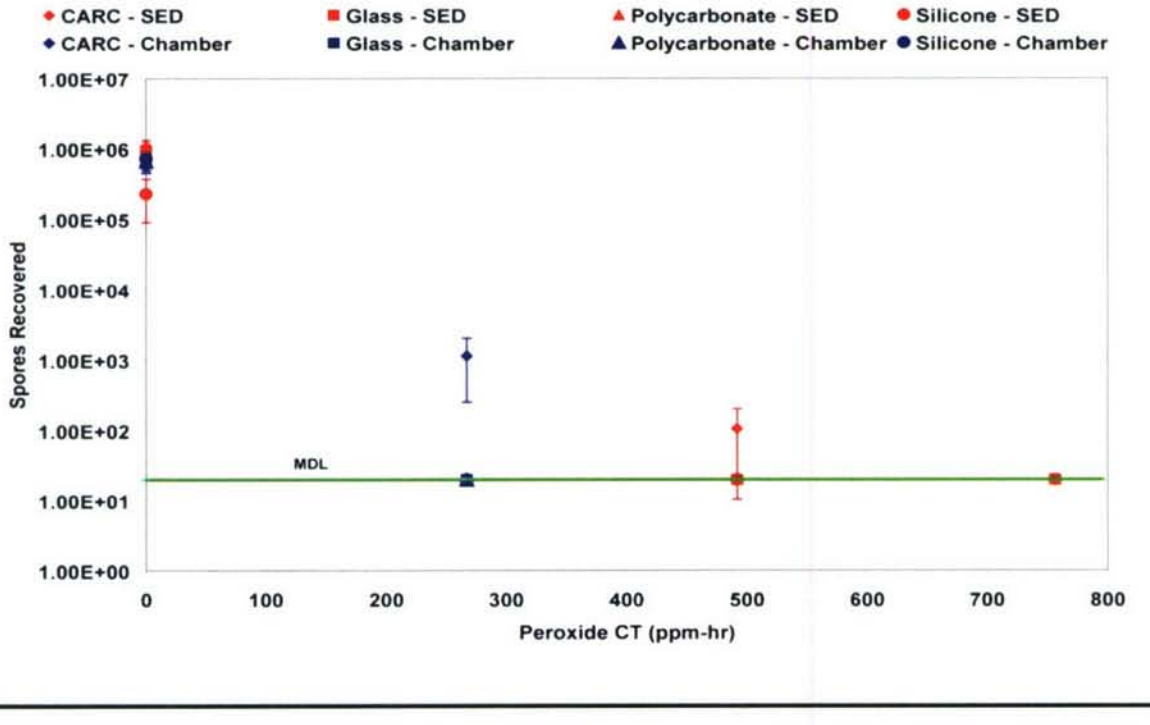


Figure 3.11.2: Target-Concentration Comparison

a) Plot in Terms of Time



b) Plot in Terms of CT



3.12 Summary of Chemical Agent Results from Lexan Replica

The primary objective of this test was to determine the mVHP system ability to decontaminate representative articles of sensitive equipment and operationally relevant materials for both biological-warfare agent surrogate contamination. At the time of the program, the plan was to retain the prototype post testing for demonstration and future evaluations. Since the unit was to be retained, only chemical agent surrogate testing could be conducted within the unit. Chemical agent surrogate testing cannot provide the same level of confidence as actual agent testing. In order to have an assessment of the system against live agent, a replica of the SED prototype decontamination chamber was constructed for use under engineering controls for live chemical agent evaluation. The chemical agent study findings and post analysis are documented under separate cover.[8,9]

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ACRONYMS AND ABBREVIATIONS

APG	Aberdeen Proving Grounds
BI	biological indicator
BSL	bio safety level
BW	biological warfare
CARC	Chemical Agent Resistant Coating
CB	chemical and biological
cfm	cubic feet minute
CFU	colony forming unit
CI	chemical indicator
CofA	certificate of analysis
CRADA	Cooperative Research and Development Agreement
CT	concentration time
CW	chemical warfare
DoD	Department of Defense
DS	Decontamination Sciences
ECBC	Edgewood Chemical Biological Center
FBS	Fetal Bovine Serum
ft	feet
H_2O_2	hydrogen peroxide
GD	nerve agent, soman
GPS	global positioning system
HD	blister agent, mustard
hr or hrs	hour or hours
IAW	in accordance with
in	inches
IOP	Internal Operating Procedure
JPID	Joint Platform Interior Decontamination
JSSED	Joint Service Sensitive Equipment Decontamination
KPP	Key Performance Parameters
LOE	Limited-Objective Experiment
min	minutes
MSDS	Material Safety Data Sheets
mVHP®, mVHP	reference to Steris' registered "modified vaporized hydrogen peroxide" procedure
NVM	night vision monocular
ORD	Operational Requirements Document
PBS	Phosphate Buffered Saline
PEL	permissible exposure limit
PI	principal investigator
PPE	personal protective equipment
ppm	parts per million
Pre-Op	pre-operational
psi	pounds per square inch

R&D	Research and Development
RDECOM	Research, Development, and Engineering Command (formerly SBCCOM)
RH	relative humidity
RRO	Risk Reduction Office
SBCCOM	Soldier and Biological Chemical Command
SD	standard deviation
SED	sensitive equipment decontamination
SOPs	standing operating procedures (standard may also be used in place of standing with the same meaning)
SOR	start of run
T	temperature
t	time
TGD	nerve agent, thickened soman
TSA	Tryptic Soy Agar
TSB	Tryptic Soy Broth
TWA	time-weighted average
µL	micro liter
VHP®, VHP	reference to Steris' registered "vaporized hydrogen peroxide" procedure
VX	nerve agent

APPENDIX A: COUPON STOCK MATERIALS AND PREPARATION

Glass
- Type: Heat-Resistant Borosilicate Glass
- Supplier: McMaster-Carr, part # 8477K12
- Stock Material: individual 2-inch diameter x 0.125 inch thick heat-resistant borosilicate sight glasses

Stainless Steel
- Type: 304
- Supplier: E-J Enterprises
- Stock Material: received as 48" x 120" sheets, 0.125" thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

Aluminum
- Type: 5052
- Supplier: E-J Enterprises
- Stock Material: received as 48" x 120" sheets, 0.125" thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

Chemical Agent Resistant Coating (CARC)-painted Aluminum
- Type: Aluminum 5052, painted with Forest Green CARC, MIL-C-53039A
- Supplier: E-J Enterprises
- Stock Material: received as 48" x 120" sheets, 0.125" thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop then painted on one face plus edges with Chemical Agent Resistant Coating, MIL-C-53039A, according to established procedures. Coupons were sterilized prior to inoculation with spores.

Polycarbonate
- Type: Clear Polycarbonate Sheet
- Supplier: E-J Enterprises, order # 0001-03460
- Stock Material: received as 48" x 96" sheets, 0.22" thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

US Air Force Topcoat Painted Aluminum

- Type: Aluminum 5052, painted with Grey USAF Topcoat, MILK-PRF-85285
- Supplier: E-J Enterprises, order #
- Stock Material: received as 48" x 120" sheets, 0.125" thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop then painted on one face plus edges with US Air Force Topcoat, MILK-PRF-85285. Coupons were sterilized prior to inoculation with spores.

Silicone Elastomer

- Type: Silicone Elastomer - Sheet MQ/VNQ/PMQ/PVMQ
- Supplier: Goodfellow, Order #089-628-36
- Stock Material: received as 500 mm x 500 mm sheets, 3.0 mm thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

Kapton®

- Type: Polyimide (PI) Film, grade Kapton HN
- Supplier: Goodfellow, order # LS257291
- Stock Material: received as 610 mm x 2 m coil, 0.125 mm thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

Viton® (Gasket Material, n-nitrile)

- Type: Hexafluoropropylene-vinylidene fluoride copolymer sheet FKM
- Supplier: Goodfellow, order # FV313300
- Stock Material: received as 300 mm x 300 mm sheets, 3.0 mm thick
- Preparation Details:
    - Biological surrogate tests: 1.3-cm squares punched at ECBC Fabrication shop. Coupons were sterilized prior to inoculation with spores.

APPENDIX B: SIMULATED SENSITIVE EQUIPMENT PHOTOGRAPHS

B.1 DVD E01

Figure B.1.1 Initial Inspection DVD Player E01

Figure B.1.2 Final Inspection DVD Player E01

B.2 DVD E02

Figure B.2.1 Initial Inspection DVD Player E02

Figure B.2.2 Final Inspection DVD Player E02

B.3 DVD E03

Figure B.3.1 Initial Inspection DVD Player E03

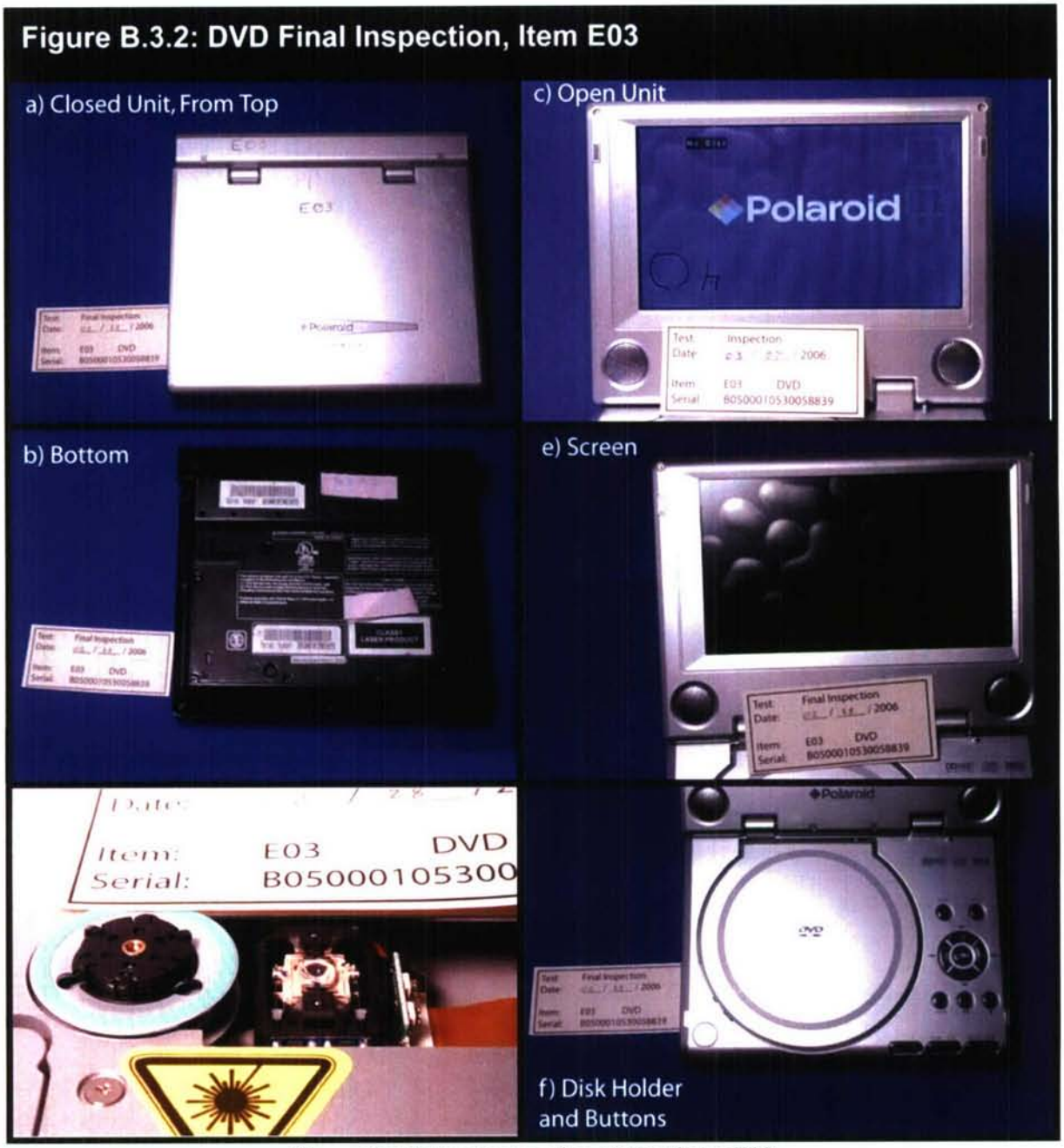

Figure B.3.2 Final Inspection DVD Player E03

B.4 DVD E04

Figure B.4.1 Initial Inspection DVD Player E04

Figure B.4.2 Final Inspection DVD Player E04

B.5 DVD E05

Figure B.5.1 Initial Inspection DVD Player E05

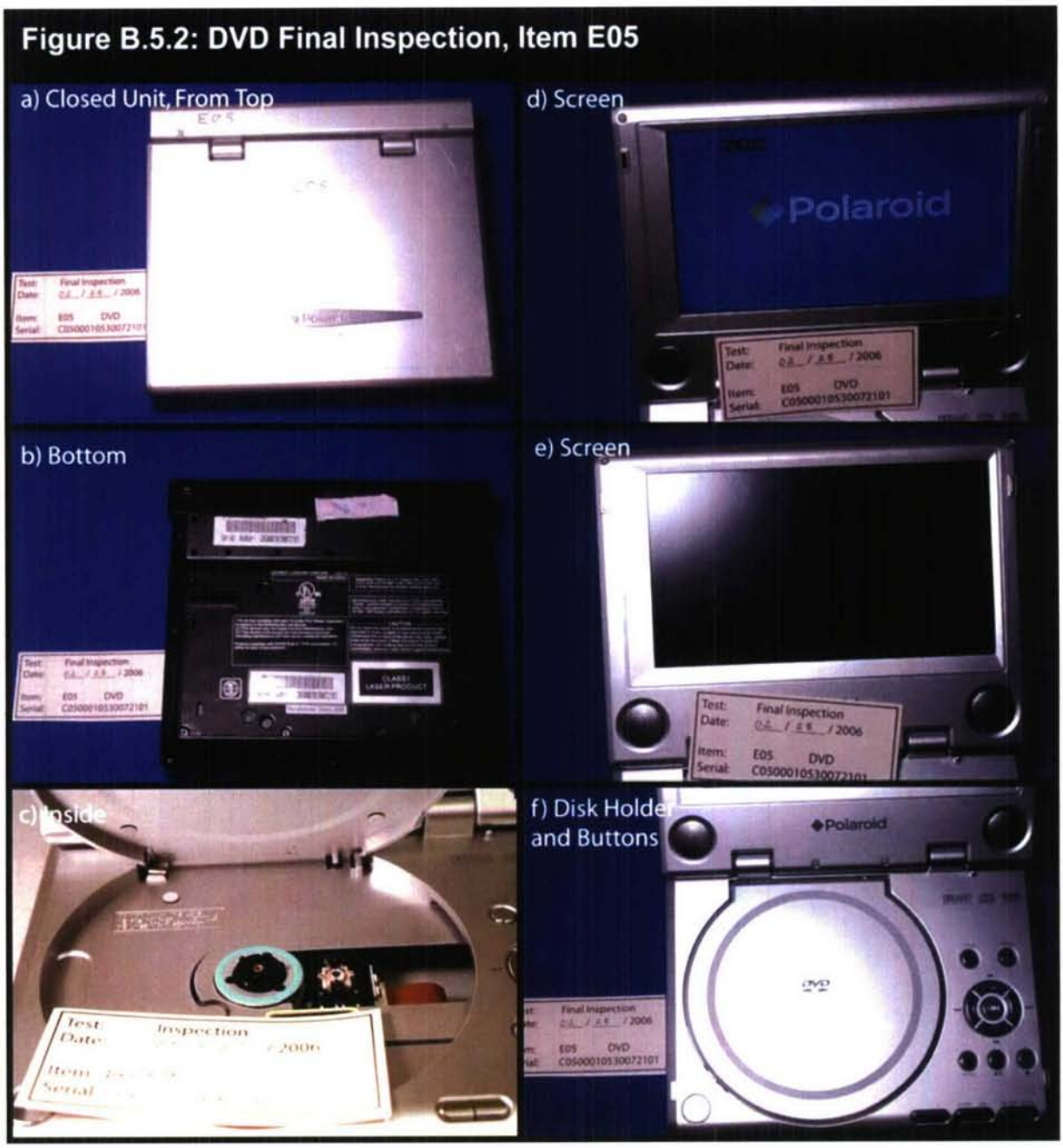

Figure B.5.2 Final Inspection DVD Player E05

B.6 DVD E06

Figure B.6.1 Initial Inspection DVD Player E06

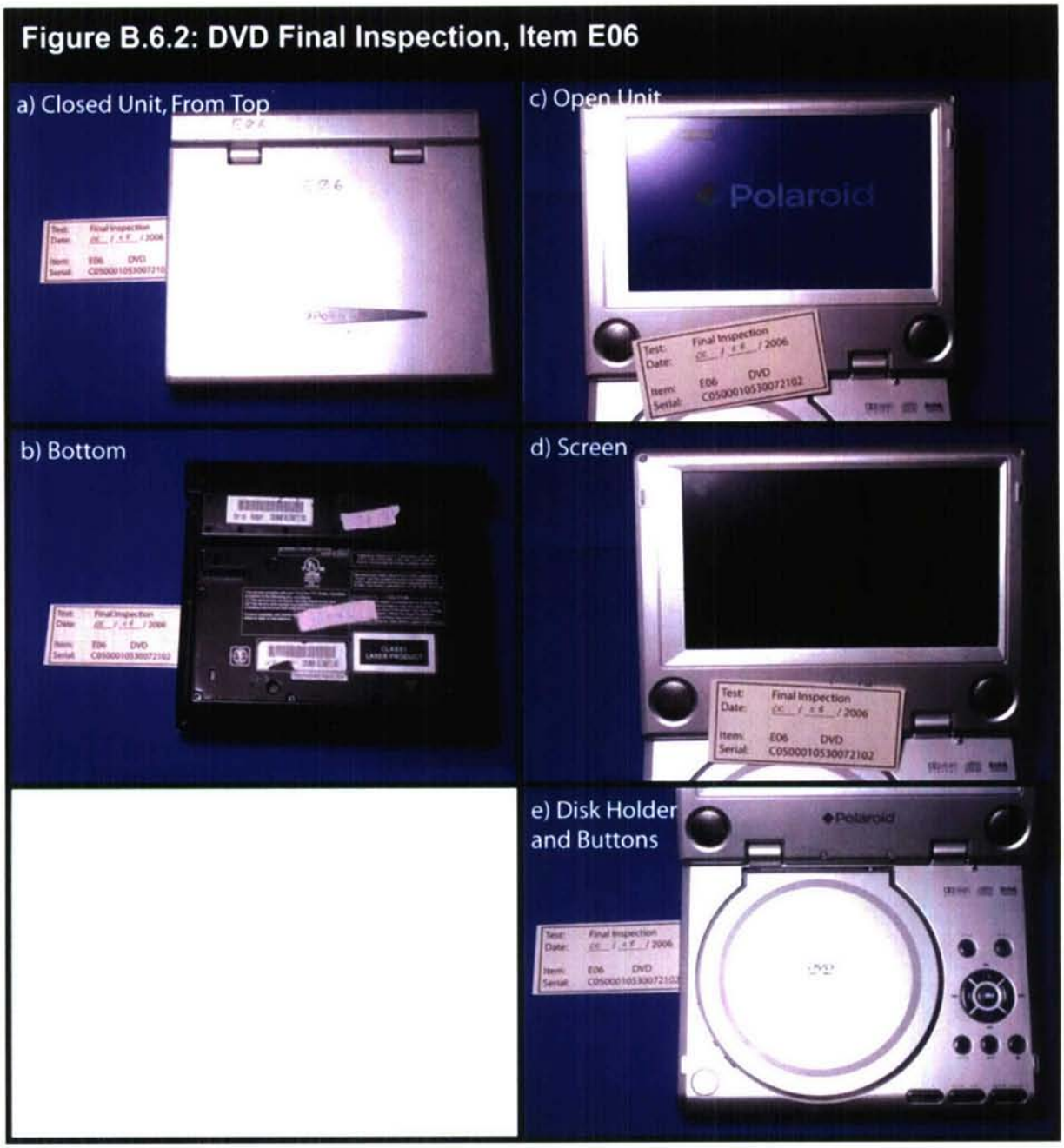

Figure B.6.2 Final Inspection DVD Player E06

B.7 Radio E07

Figure B.7.1 Initial Inspection Radio E07

Figure B.7.2 Final Inspection Radio E07

B.8 Radio E08

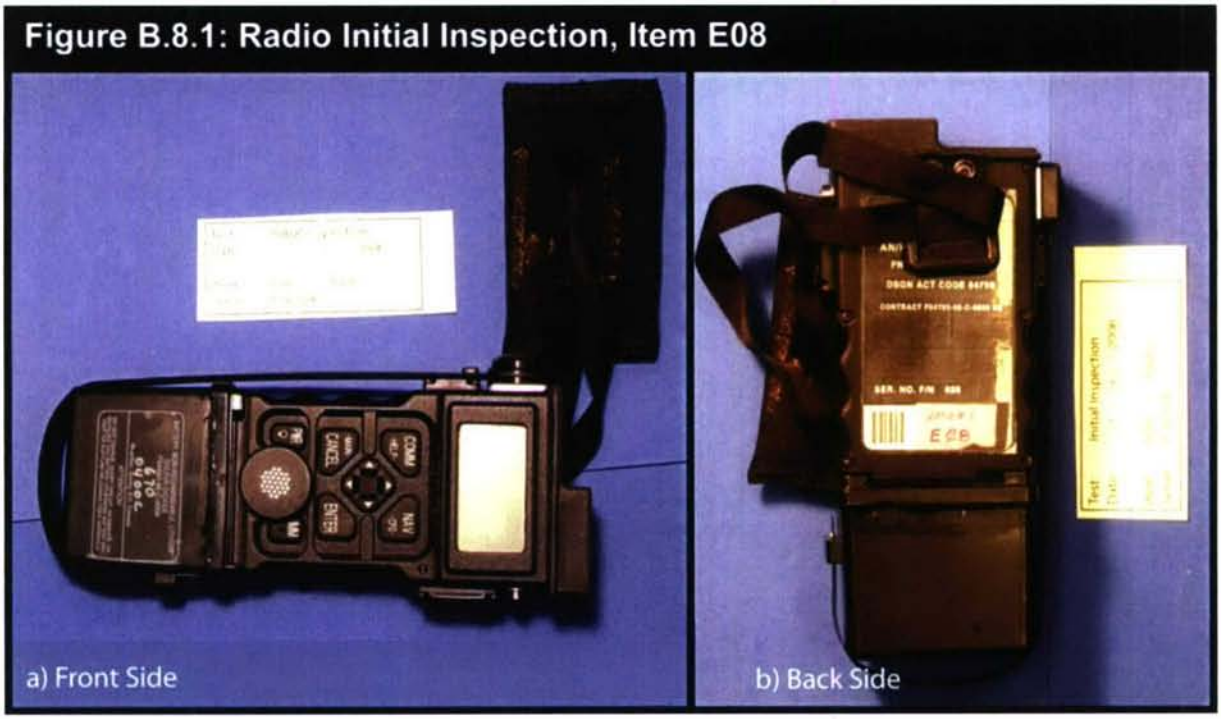

Figure B.8.1 Initial Inspection Radio E08

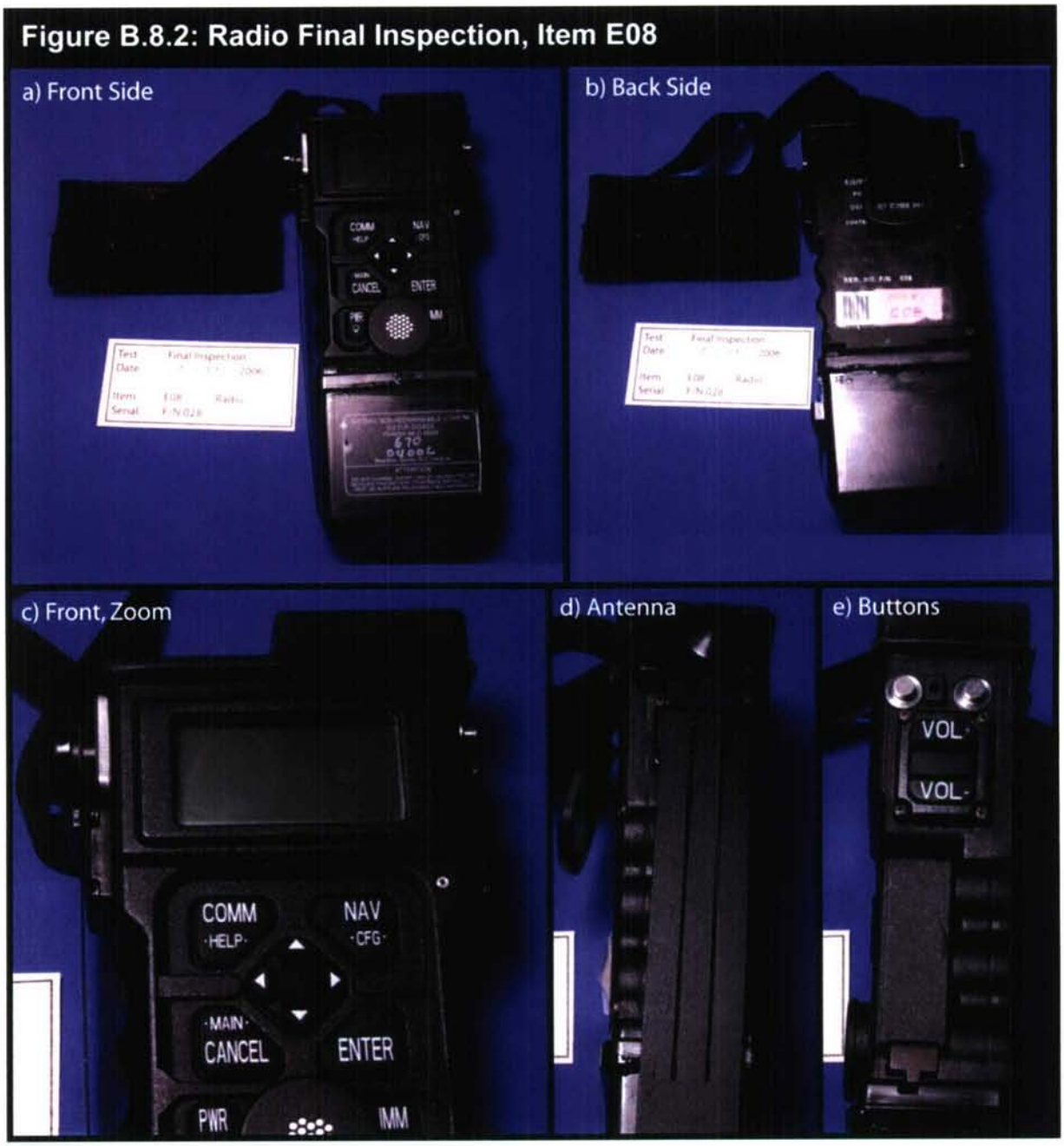

Figure B.8.2 Final Inspection Radio E08

B.9 Radio E09

Figure B.9.1 Initial Inspection Radio E09

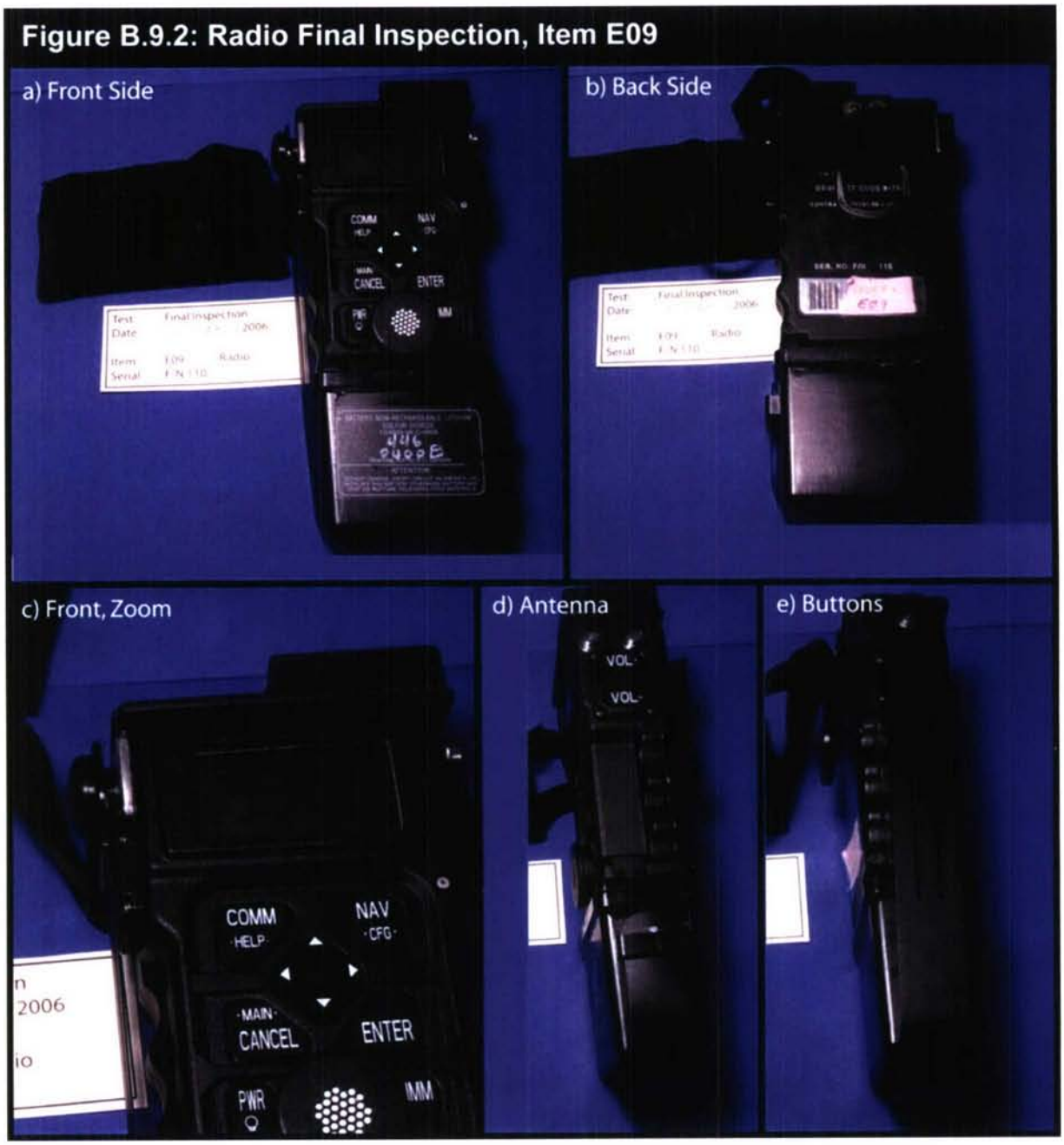

Figure B.9.2 Final Inspection Radio E09

B.10 Radio E10

Figure B.10.1 Initial Inspection Radio E10

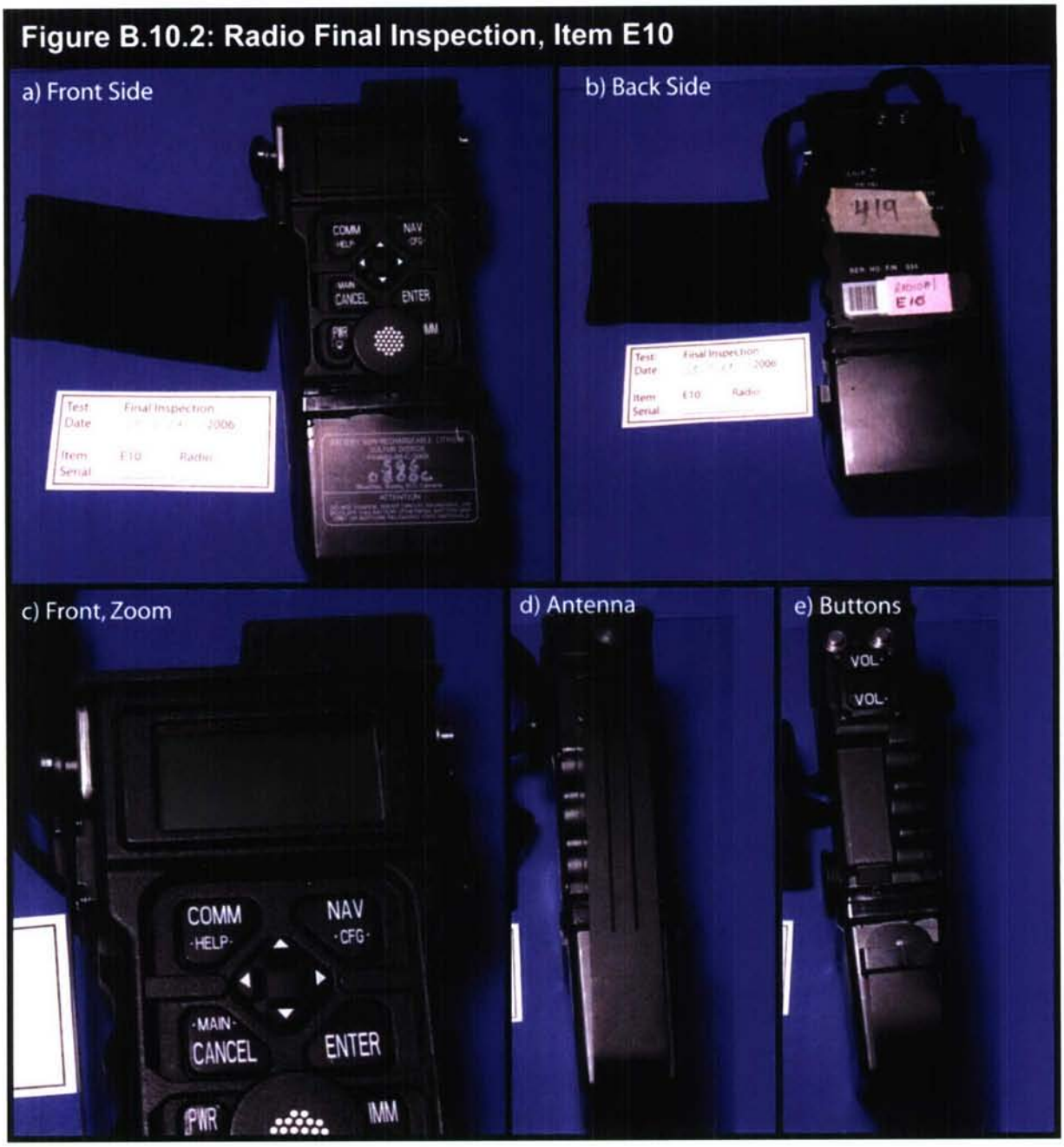

Figure B.10.2 Final Inspection Radio E10

B.11 Night Vision Monocular E11

Figure B.11.1 Initial Inspection Night Vision Monocular E11

Figure B.11.2 Final Inspection Night Vision Monocular E11

B.12 Night Vision Monocular E12

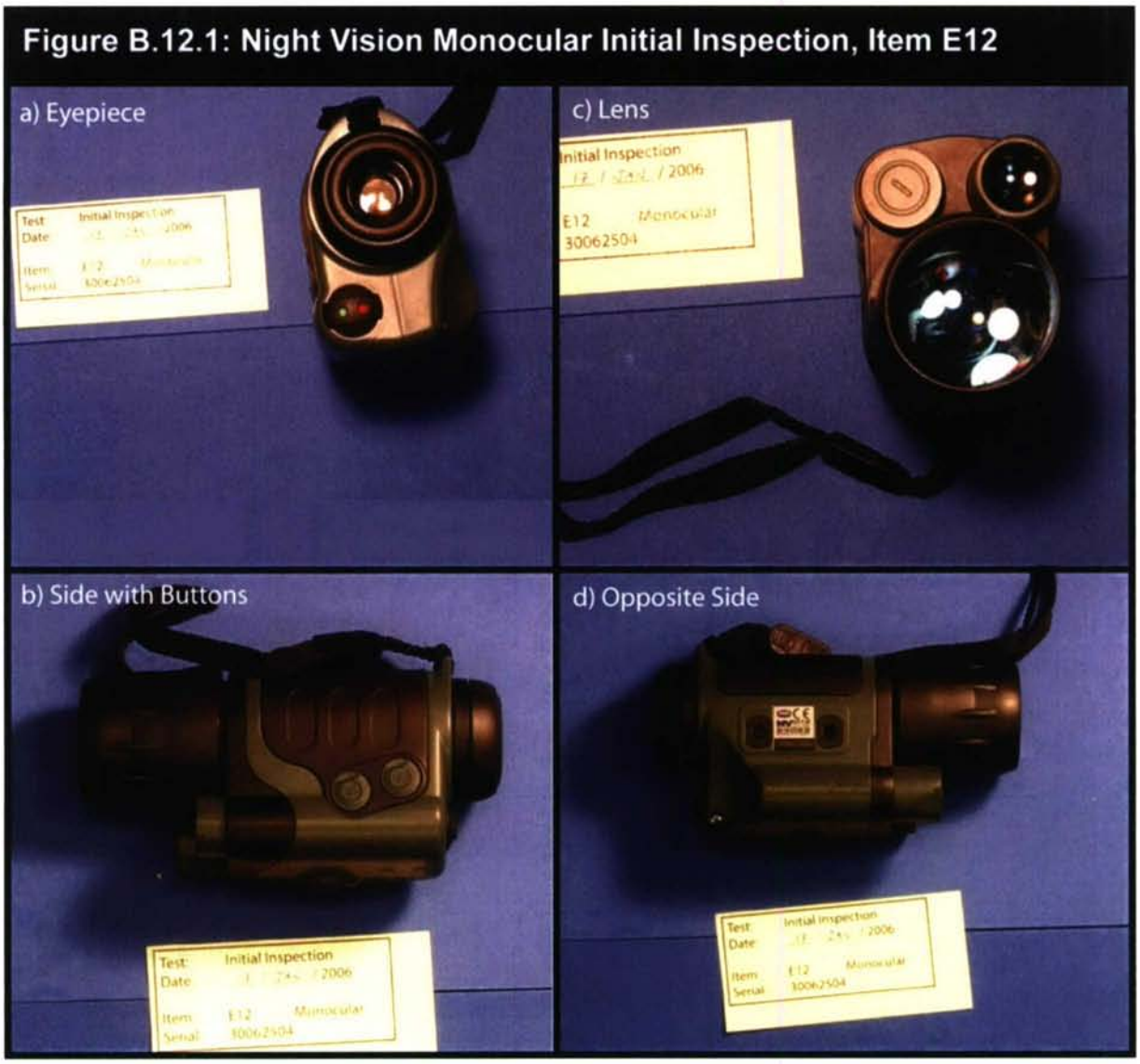

Figure B.12.1 Initial Inspection Night Vision Monocular E12

Figure B.12.2 Final Inspection Night Vision Monocular E12

B.13 Night Vision Monocular E13

Figure B.13.1 Initial Inspection Night Vision Monocular E13

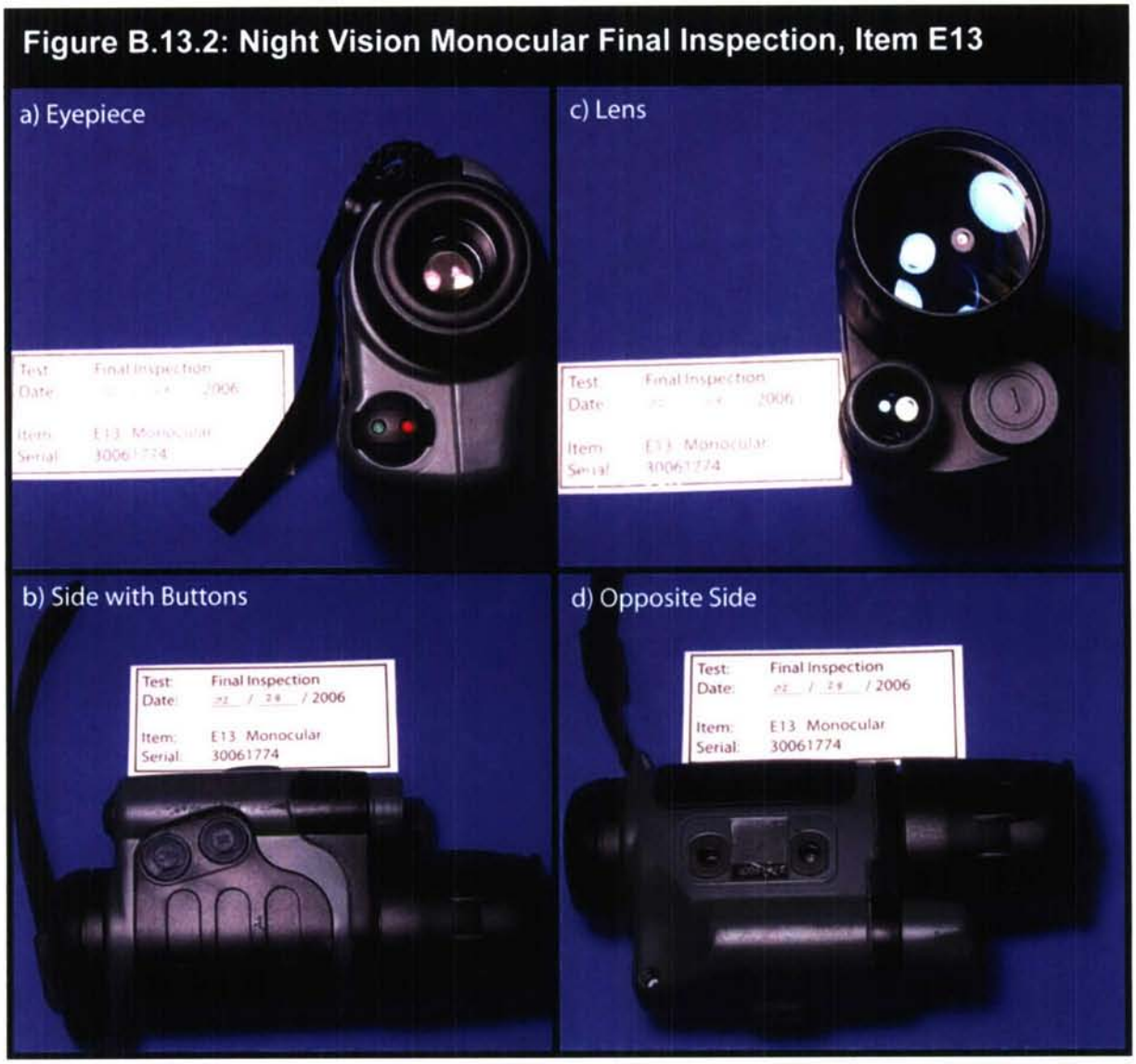

Figure B.13.2 Final Inspection Night Vision Monocular E13

B.14 Night Vision Monocular E14

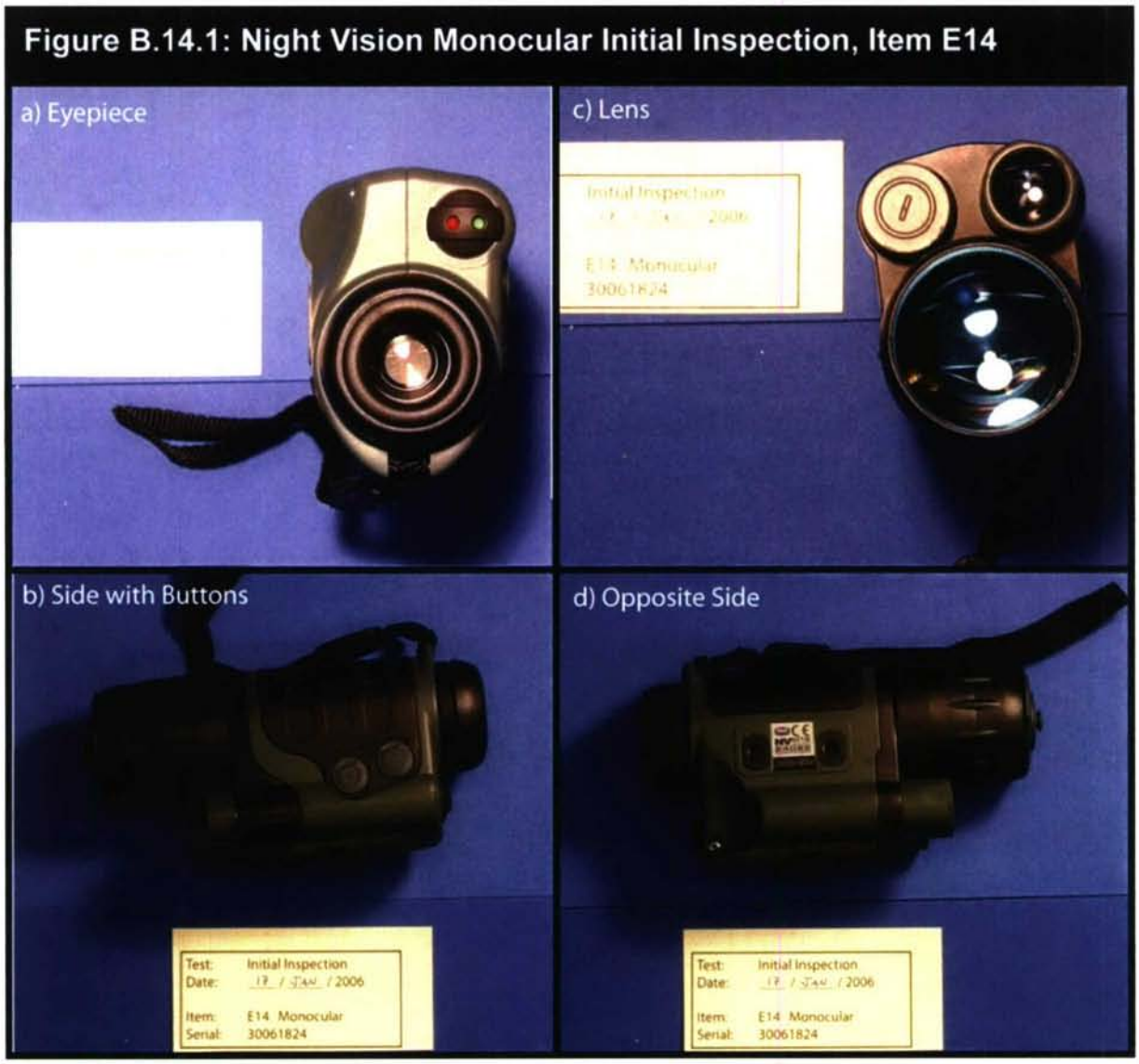

Figure B.14.1 Initial Inspection Night Vision Monocular E14

Figure B.14.2 Final Inspection Night Vision Monocular E14

B.15 GPS Unit E15

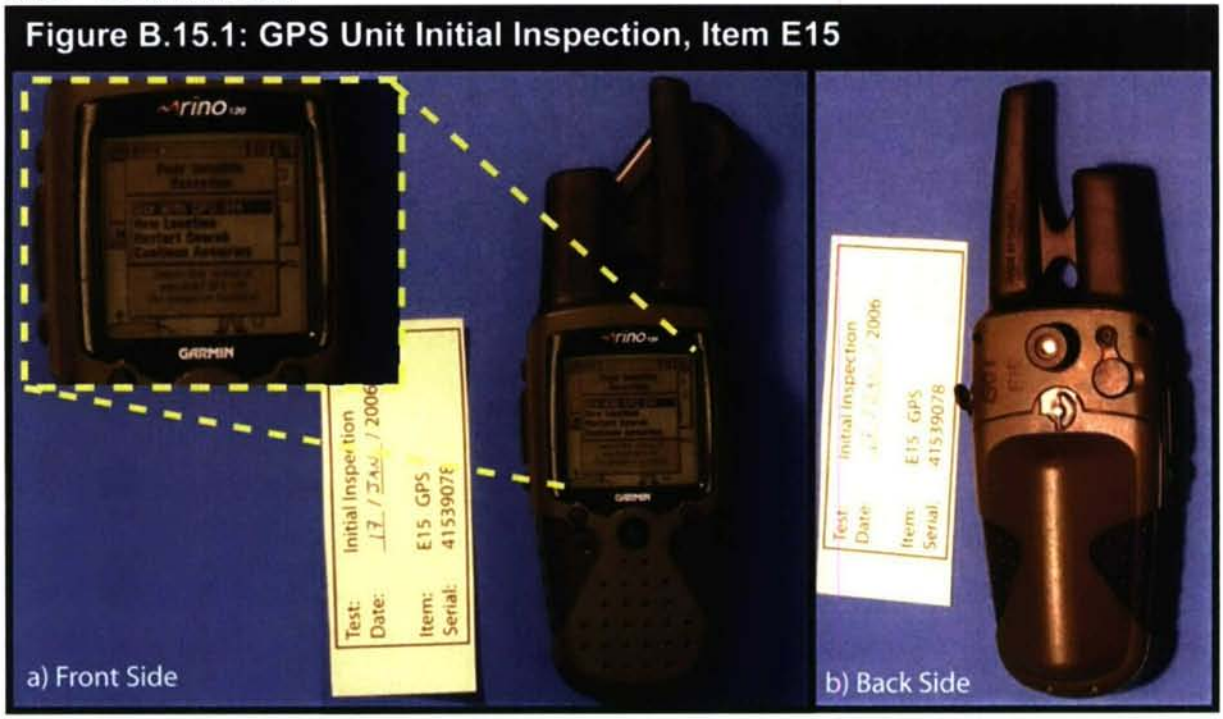

Figure B.15.1 Initial Inspection GPS Unit E15

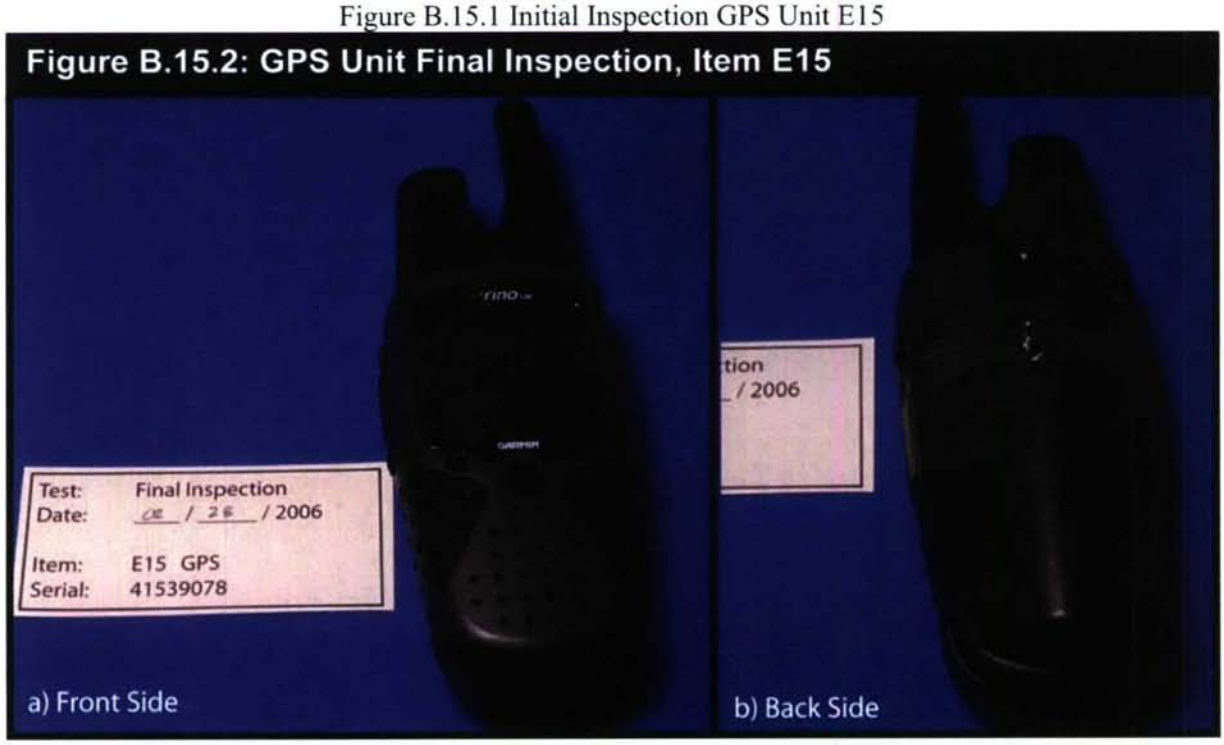

Figure B.15.2 Final Inspection GPS Unit E15

B.16 GPS Unit E16

Figure B.16.1 Initial Inspection GPS Unit E16

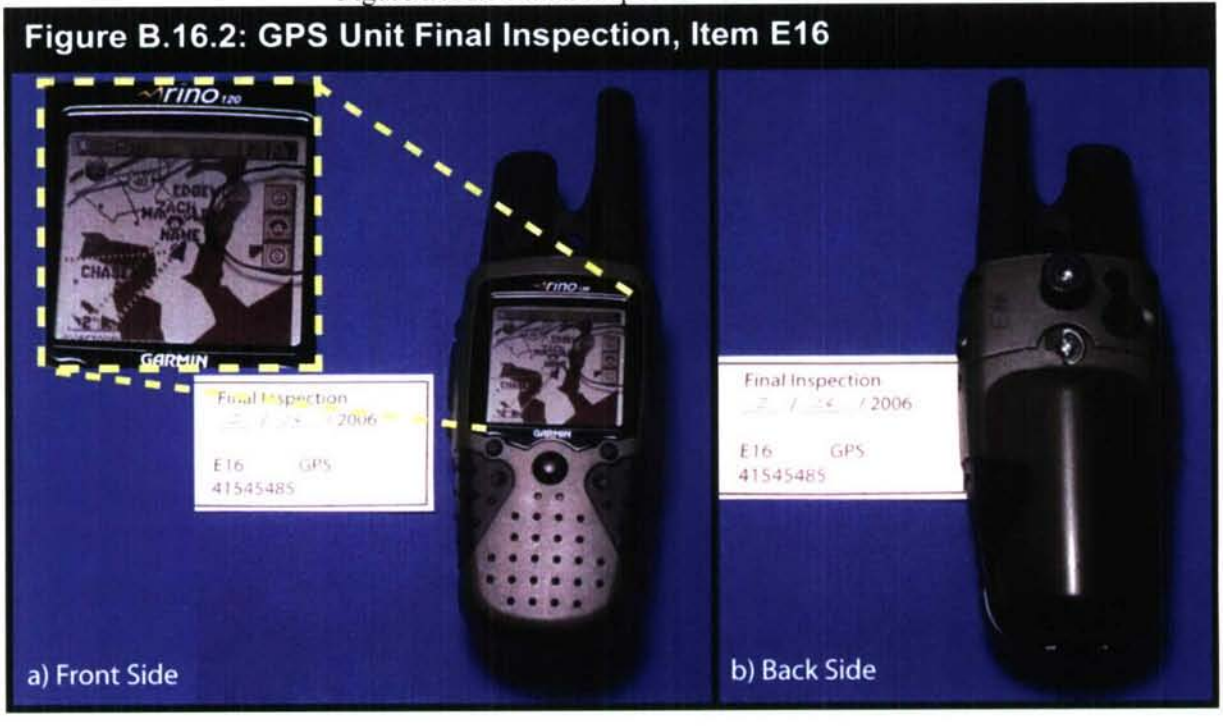

Figure B.16.2 Final Inspection GPS Unit E16

B.17 GPS Unit E17

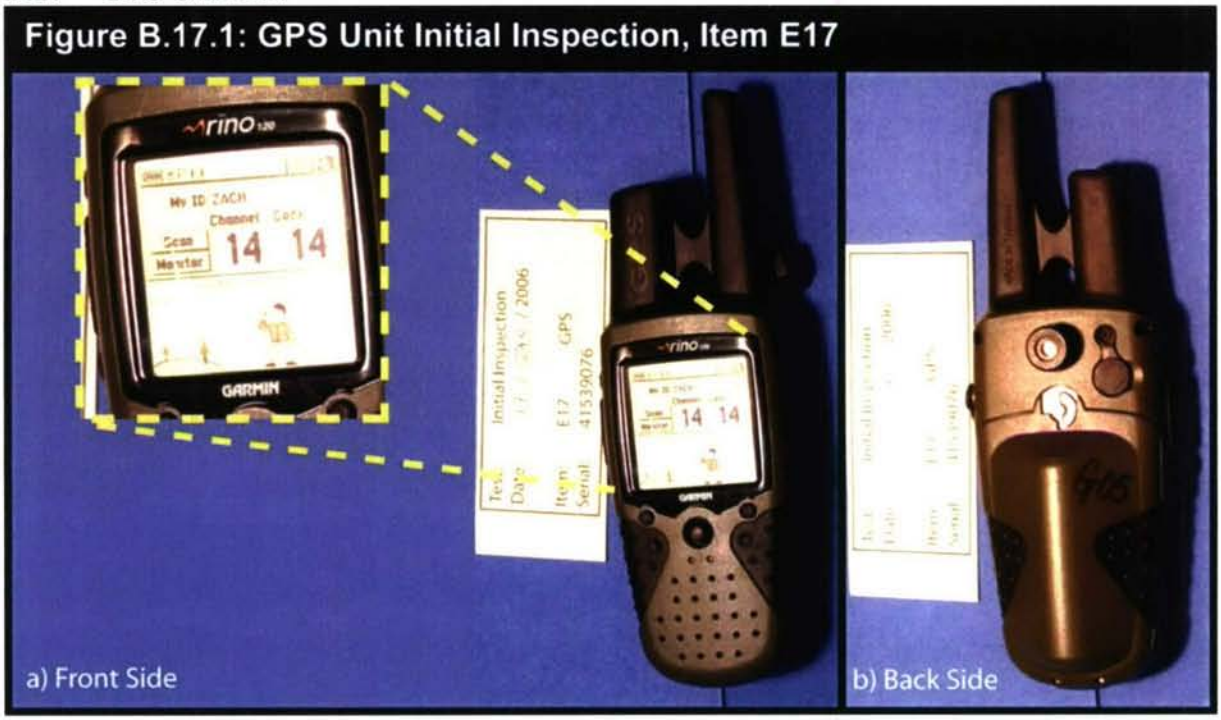

Figure B.17.1 Initial Inspection GPS Unit E17

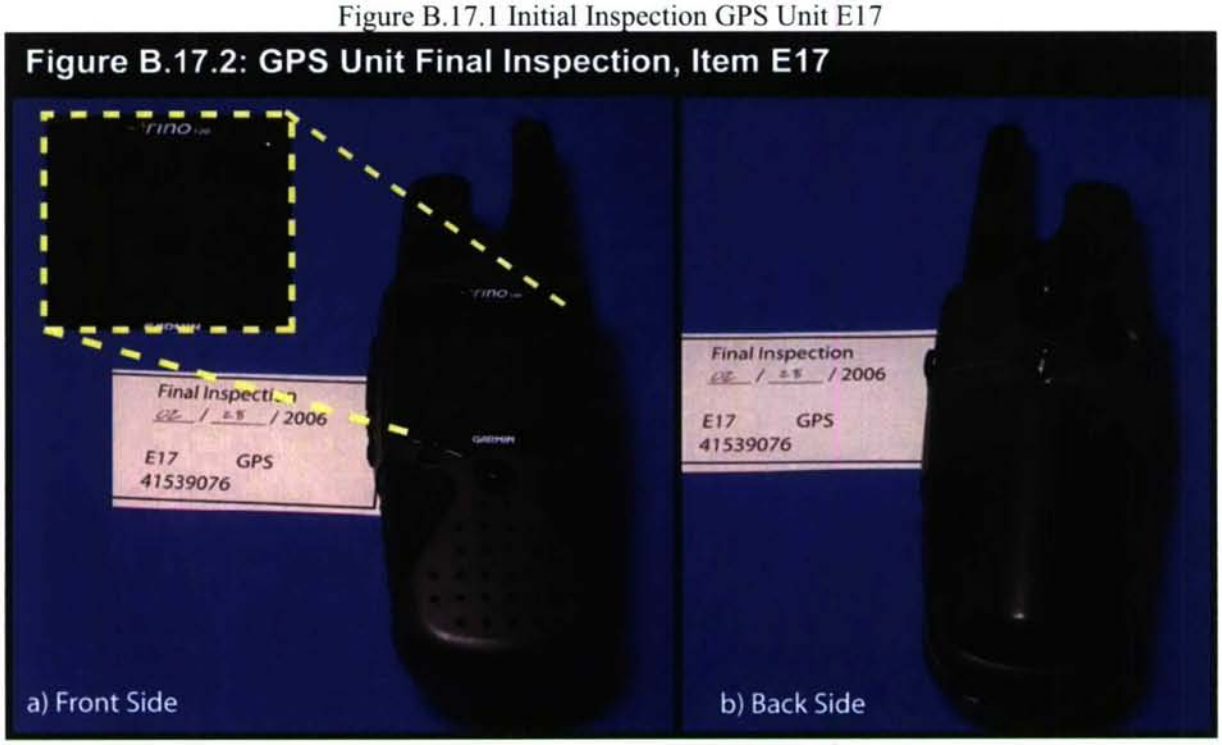

Figure B.17.2 Final Inspection GPS Unit E17

B.18 GPS Unit E18

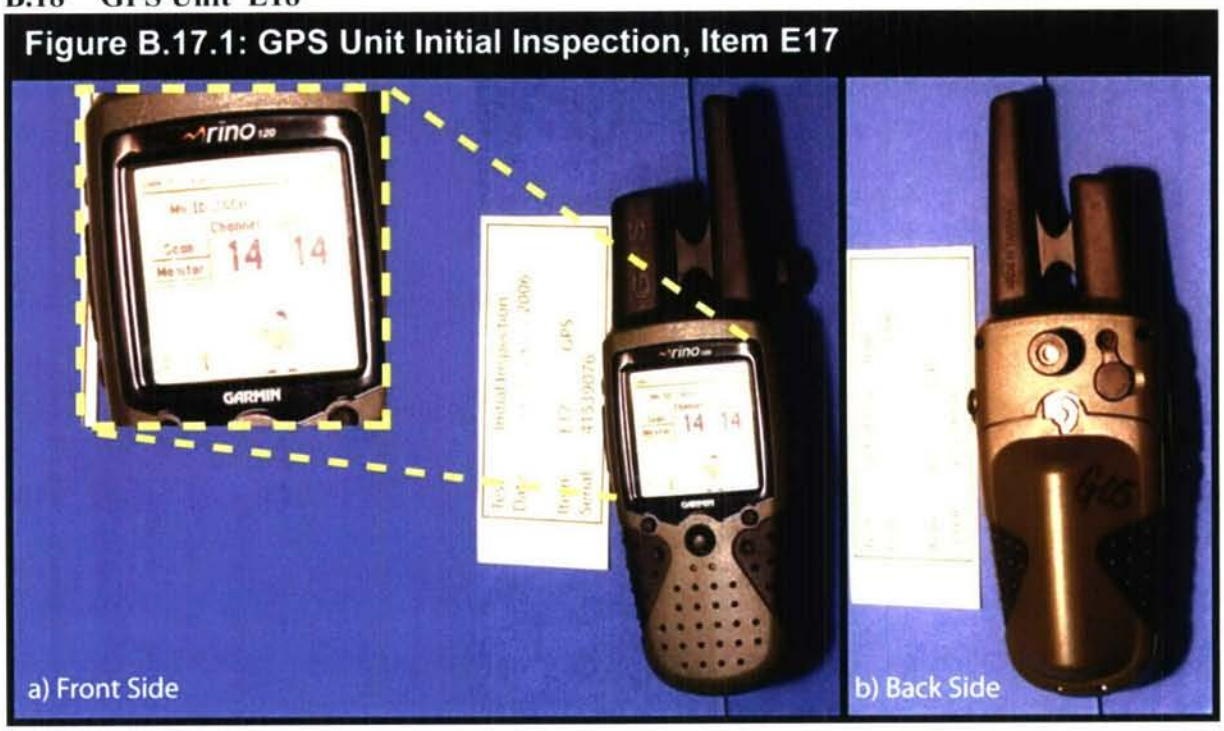

Figure B.18.1 Initial Inspection GPS Unit E18

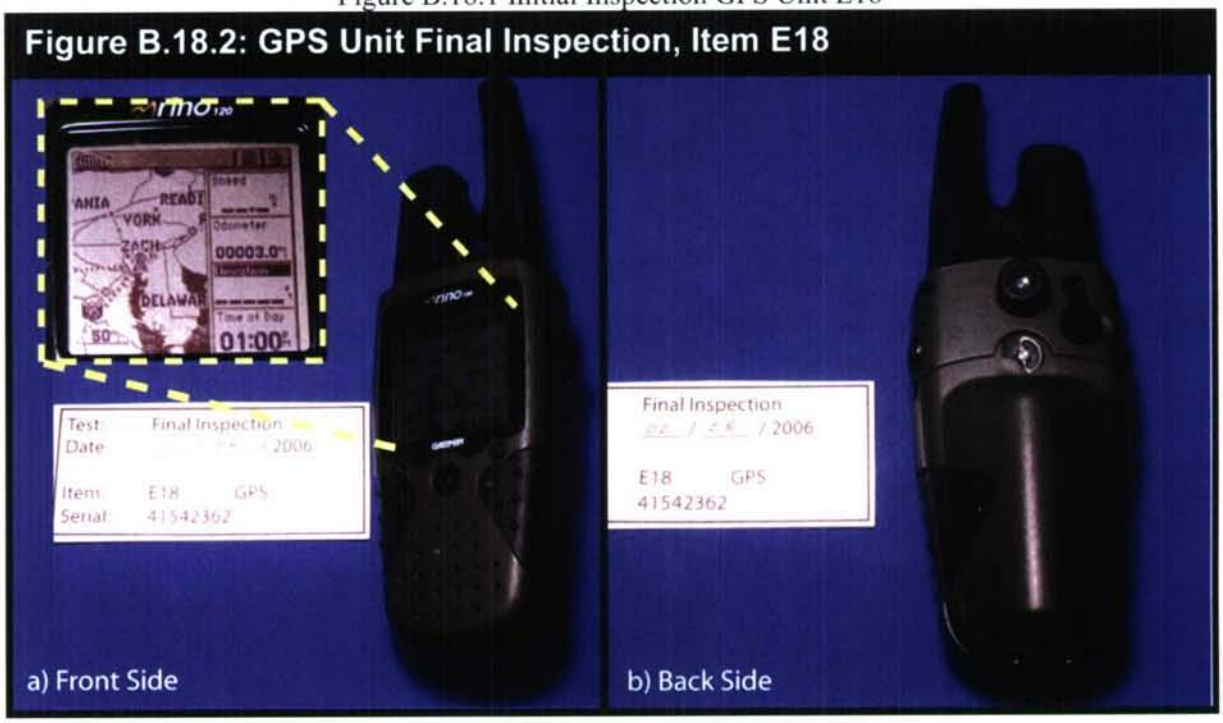

Figure B.18.2 Final Inspection GPS Unit E18

B.19 GPS Unit E19

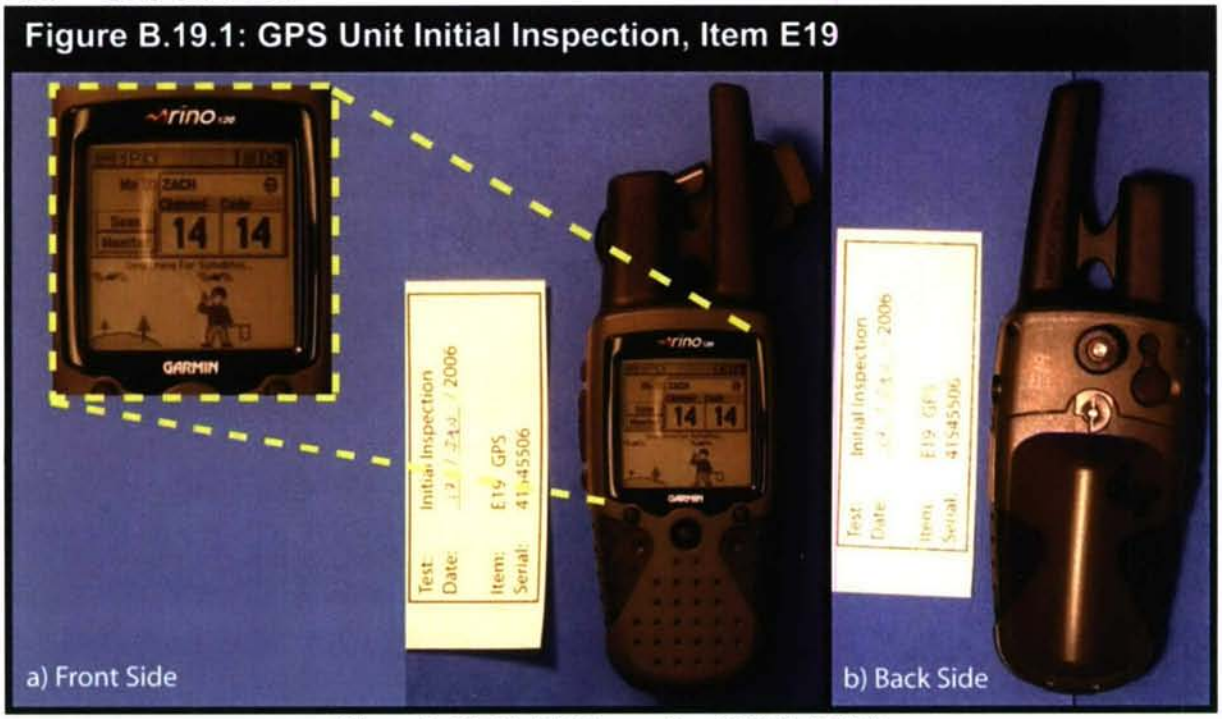

Figure B.19.1 Initial Inspection GPS Unit E19

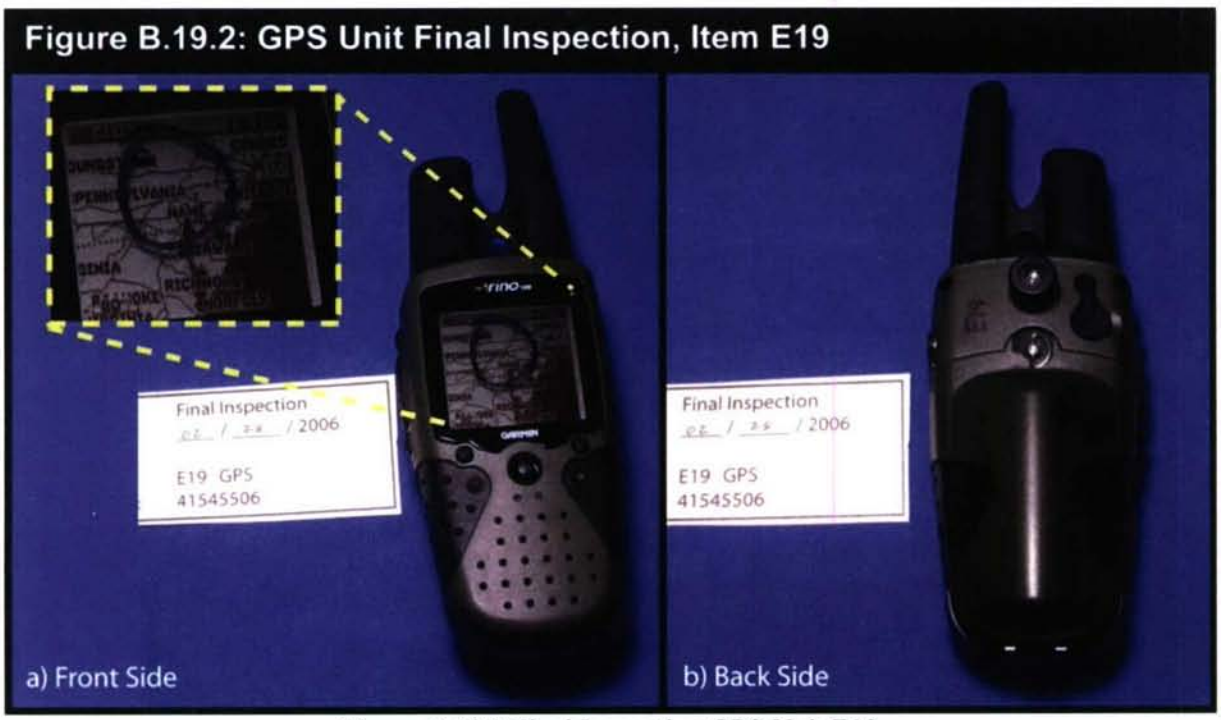

Figure B.19.2 Final Inspection GPS Unit E19

B.20 Desktop Computer E20

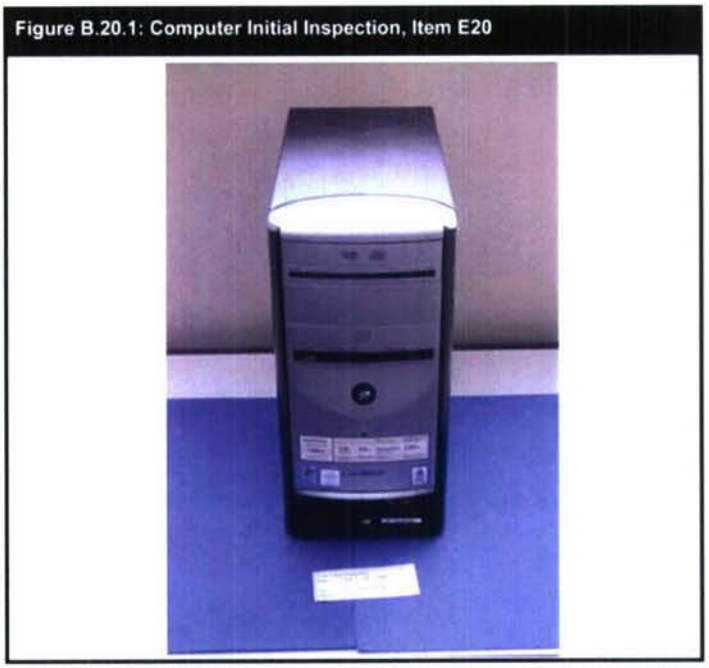

Figure B.20.1 Initial Inspection Desktop Computer E20

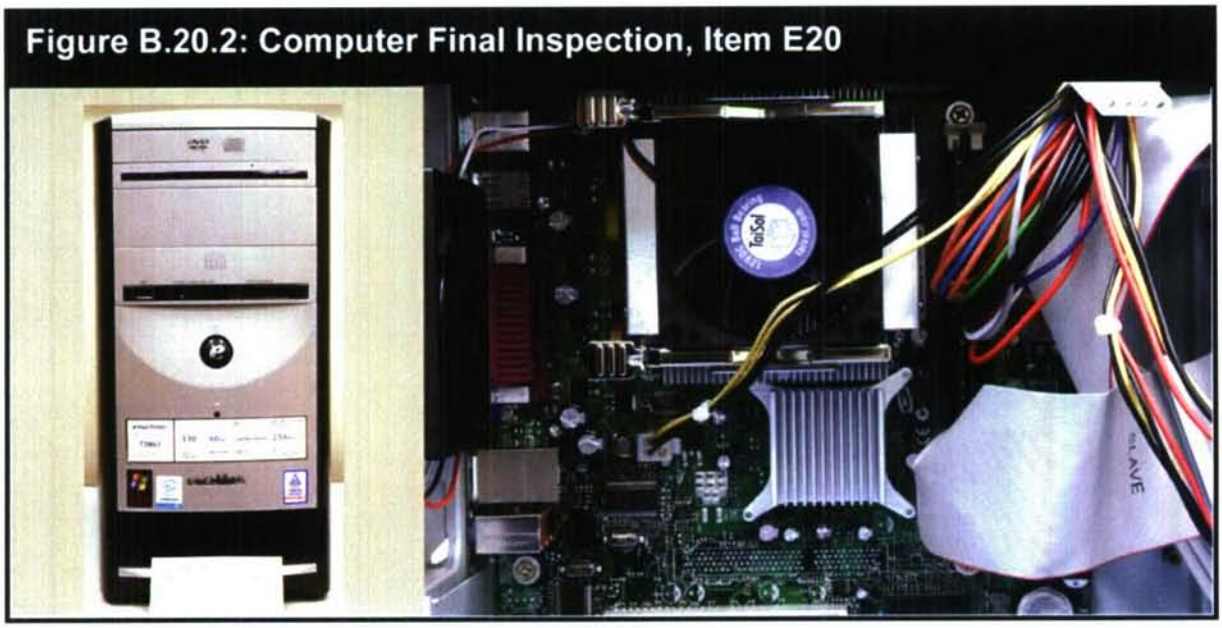

Figure B.20.2 Final Inspection Desktop Computer E20

B.21 Mask E21

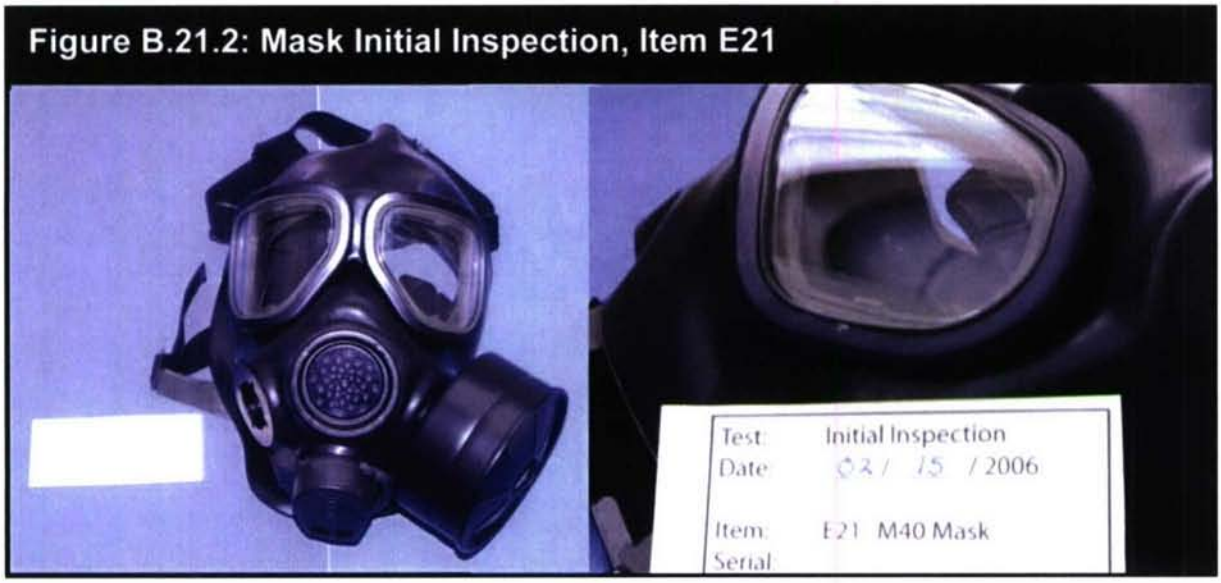

Figure B.21.1 Initial Inspection Mask E21

Figure B.21.2 Final Inspection Mask E21

APPENDIX C: SED TEST CONTROL CHARTS

Table C.1: Summary Cycle Information

Cycle Number	Run Type eng cube bio chem aborted	Comments	Setpoints			DH time min	CD time min	DC time min	A time min	Actual										CT Ratio
			H2O2 (set) ppm	NH3 (set) ppm	controlling sensor (top shelf both)					H2O2 top ave ppm	NH3 top ave ppm	H2O2 shelf ave ppm	NH3 shelf ave ppm	H2O2 CT shelf	NH3 CT shelf	DH time min	CD time min	DC time min	A time min	NH3/ peroxide
243	Cube	Peroxide Test Strips (both types) placed on Tupperware "cubes"	500	0	shelf	1	1	60	1	463.1 ± 55.6	0.0 ± 0.0	504.8 ± 55.4	0.0 ± 0.0	679.7	0.1	5	8	60	96	0.01%
244	Cube	Peroxide Test Strips (both types) placed on Tupperware "cubes"	500	0	shelf	1	1	30	1	514.5 ± 29.7	0.0 ± 0.0	499.2 ± 25.2	0.5 ± 0.9	407.4	1.8	7	16	30	71	0.44%
245	Cube	Peroxide Test Strips (both types) placed on Tupperware "cubes"	750	0	shelf	1	1	30	1	773.0 ± 16.9	0.0 ± 0.0	739.6 ± 22.0	16 ± 0.5	746.3	5.2	10	18	30	133	0.70%
304	Bio	Equipment contaminated with *G. Stearo*	500	30	shelf	1	1	80	15	451.2 ± 20.5	29.6 ± 1.4	497.4 ± 22.7	32.7 ± 2.8	729.6	47.7	7	4	80	21	6.54%
305	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	200	15	451.2 ± 19.1	30.6 ± 1.1	500.2 ± 17.1	34.0 ± 4.3	1742.3	115.6	5	3	200	50	6.63%
306	Bio	*G Stearo* coupons	500	30	shelf	1	1	80	15	461.4 ± 15.1	30.6 ± 1.2	501.2 ± 11.6	32.2 ± 2.1	756.3	47.3	7	4	80	61	6.25%
307	Bio	*G Stearo* coupons	0	0	shelf	1	1	80	15	19.5 ± 1.9	1.8 ± 0.4	24.7 ± 2.6	1.1 ± 0.5	39.5	1.6	5	1	80	15	4.05%
308	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	15	457.3 ± 17.2	37.0 ± 5.0	499.6 ± 15.8	32.6 ± 2.4	4248.6	272.9	5	3	500	63	6.42%
310	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	200	15	452.4 ± 25.5	38.3 ± 1.6	498.8 ± 16.9	32.8 ± 2.3	1752	111.4	3	3	200	68	6.36%
311	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	15	476.1 ± 23.9	48.9 ± 7.4	499.0 ± 19.3	31.7 ± 1.9	4249.6	265.0	5	2	500	72	6.24%
315	Bio	*G. Stearo* coupons	500	30	shelf	1	1	50	15	427.4 ± 21.6	33.5 ± 1.6	501.5 ± 20.8	31.4 ± 1.1	492.3	32.6	5	5	50	43	6.62%
317	Bio	*G. Stearo* coupons	250	15	shelf	1	1	50	15	223.8 ± 15.8	21.0 ± 1.7	249.5 ± 17.5	18.1 ± 2.3	251	20.1	1	2	50	62	8.01%
318	Bio	Equipment contaminated with *G. Stearo*	500	30	shelf	1	1	110	20	452.2 ± 26.7	33.6 ± 1.1	498.8 ± 16.0	32.2 ± 1.6	1015.9	66.4	7	7	110	46	6.54%
319	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	20	466.0 ± 11.7	36.4 ± 3.3	500.7 ± 10.4	31.8 ± 1.6	4273.3	276.6	6	4	500	70	6.47%

Table C.1: Summary Cycle Information (continued)			Setpoints							Actual										CT Ratio
Cycle Number Number	Run Type eng, cube, bio, chem, aborted	Comments	H_2O_2 (set) ppm	NH_3 (set) ppm	controlling sensor (top, shelf, both)	DH time min	CD time min	DC time min	A time min	H_2O_2 top ave, ppm	NH_3 top ave, ppm	H_2O_2 shelf ave, ppm	NH_3 shelf ave, ppm	H_2O_2 CT shelf	NH_3 CT shelf	DH time min	CD time min	DC time min	A time min	NH_3/ peroxide
320	Bio	Equipment contaminated with *G. Stearo*	500	30	shelf	1	1	80	20	486.5 ± 15.6	36.4 ± 0.9	500.2 ± 12.4	30.7 ± 0.9	1339.1	78.4	34	75	80	60	5.85%
321	Equipment	Electronic Equipment, no contamination Ammonia bottle ran out ~halfway through run	500	30	shelf	1	1	740	20	480.8 ± 12.8	32.3 ± 16.0	499.9 ± 9.0	18.1 ± 15.2	6315.8	235.2	5	4	740	179	3.72%
322	Bio	Equipment contaminated with *G. Stearo*	500	30	shelf	1	1	80	20	480.5 ± 25.1	37.2 ± 1.4	498.9 ± 19.0	33.6 ± 2.6	811.6	57.8	7	4	80	131	7.12%
323	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	740	20	493.7 ± 20.6	51.2 ± 10.3	499.5 ± 10.6	32.3 ± 2.6	6276.2	400.6	6	4	740	92	6.38%
324	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	350	20	501.2 ± 10.7	55.7 ± 3.1	499.6 ± 12.8	33.0 ± 3.8	2962.4	194.5	6	3	350	10	6.57%
330	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	350	20	510.1 ± 15.8	36.0 ± 2.5	500.2 ± 8.2	34.8 ± 4.5	2979.4	205.8	4	3	350	20	6.91%
331	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	740	20	508.4 ± 7.6	60.3 ± 12.4	499.9 ± 5.7	32.7 ± 4.8	6264.8	404.6	1	2	740	78	6.46%
332	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	320	20	512.1 ± 23.8	47.0 ± 2.6	500.7 ± 10.0	33.7 ± 3.4	2782.6	183.1	7	5	320	79	6.58%
333	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	20	501.1 ± 20.4	46.9 ± 4.5	499.6 ± 10.2	34.2 ± 3.7	4272.4	288.5	7	5	500	77	6.75%
334	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	20	520.2 ± 18.2	29.9 ± 6.9	500.4 ± 10.5	18.8 ± 8.7	4360.5	170.7	7	4	500	342	3.91%
335	Equipment	Electronic Equipment, no contamination	500	30	shelf	1	1	500	20	499.6 ± 16.6	35.8 ± 2.7	499.4 ± 8.9	34.2 ± 3.1	4258.3	288.8	7	5	500	60	6.78%
336	Eng	300 x - 6-inch cubes	500	0	shelf	1	1	80	20	668.7 ± 167.7	11.0 ± 1.0	555.1 ± 111.0	7.1 ± 1.3	944.3	19.7	34	16	80	78	2.09%
337	Eng	300 x - 6-inch cubes	500	0	shelf	1	1	50	20	558.8 ± 57.2	12.2 ± 0.5	503.1 ± 29.1	7.3 ± 0.9	652.3	25.9	5	3	50	420	3.97%
339	Eng	300 x - 6-inch cubes	500	30	shelf	1	1	80	20	518.2 ± 50.9	34.3 ± 1.5	493.8 ± 49.1	36.3 ± 4.9	814.9	63.8	6	7	80	146	7.83%

C.1 Control Chart for Cycle 304

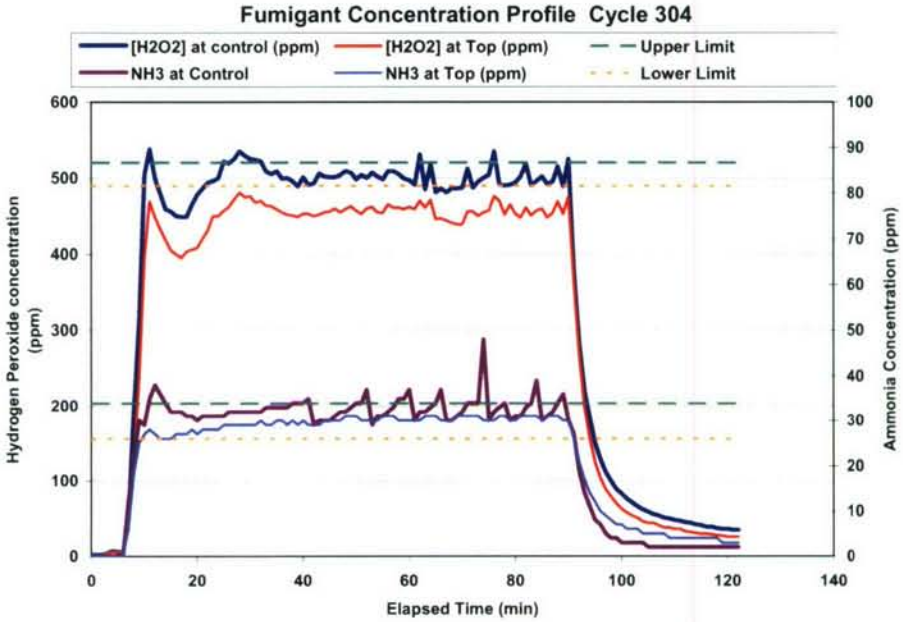

Figure C.1.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 304

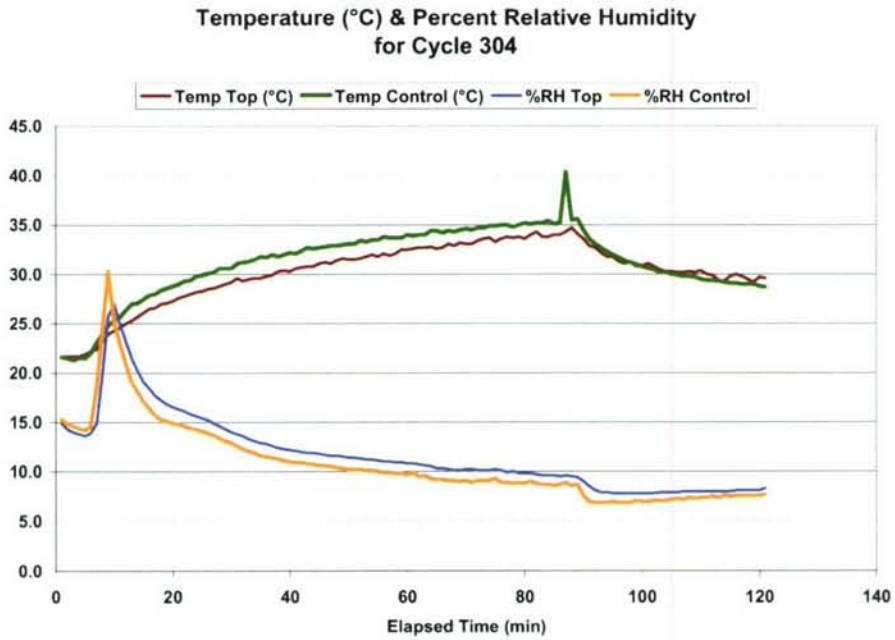

Figure C.1.2 Relative Humidity and Temperature Control Chart Cycle 304

C.2 Control Chart for Cycle 305

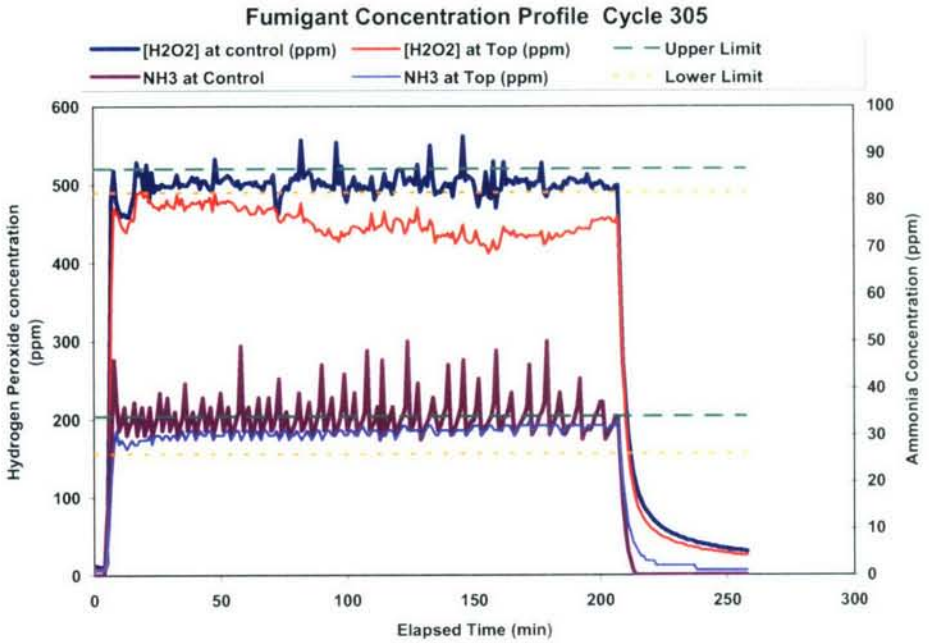

Figure C.2.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 305

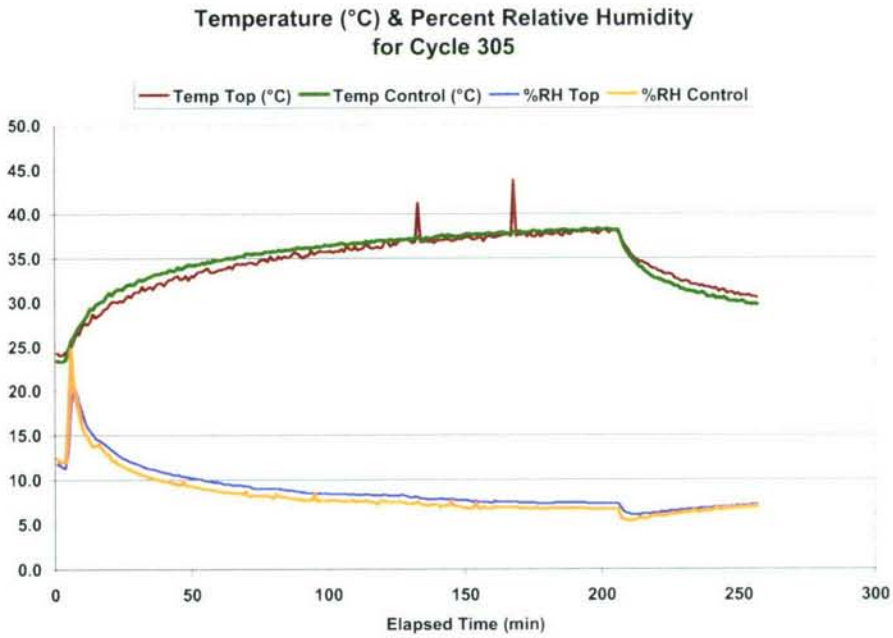

Figure C.2.2 Relative Humidity and Temperature Control Chart Cycle 305

C.3 Control Chart for Cycle 306

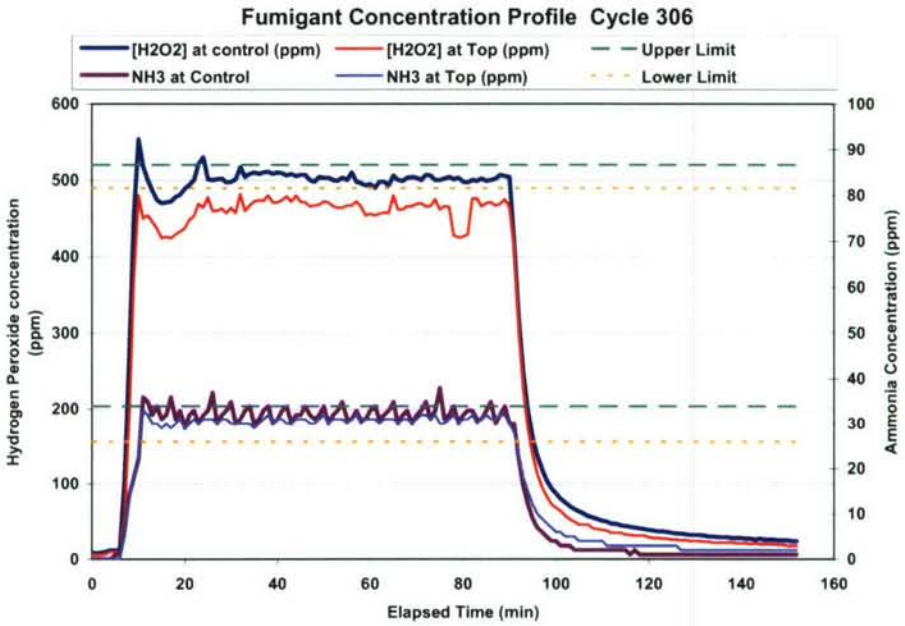

Figure C.3.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 306

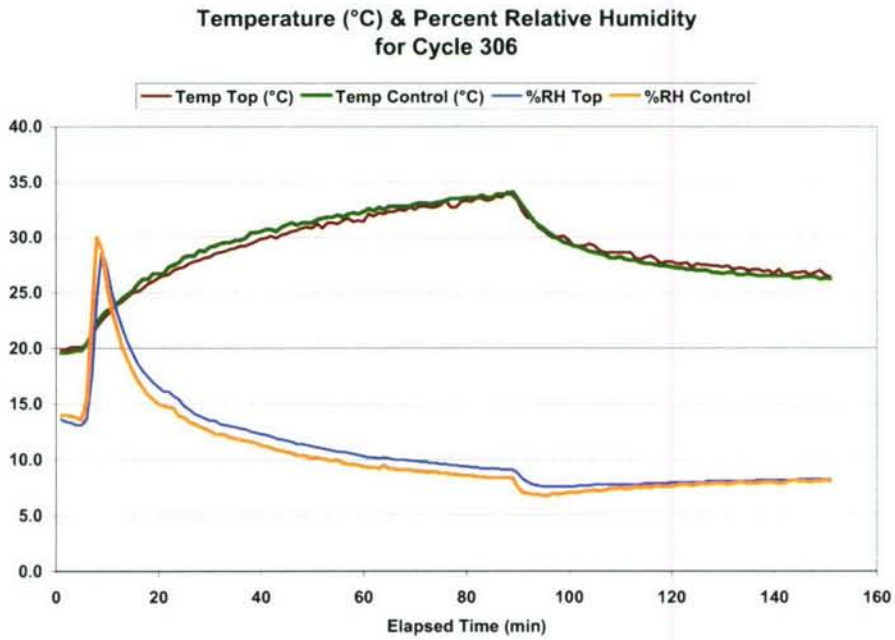

Figure C.3.2 Relative Humidity and Temperature Control Chart Cycle 306

C.4 Control Chart for Cycle 307

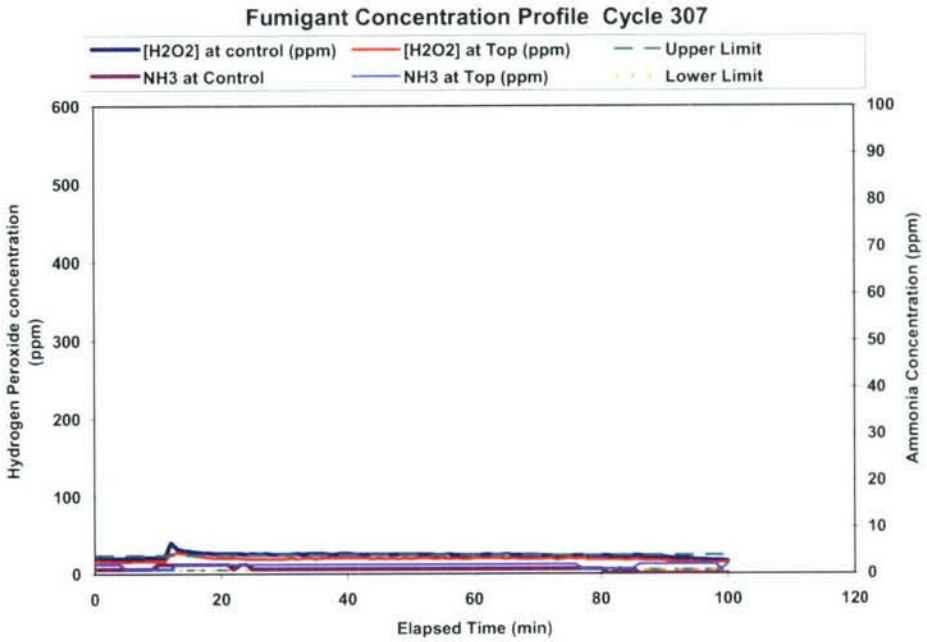

Figure C.4.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 307

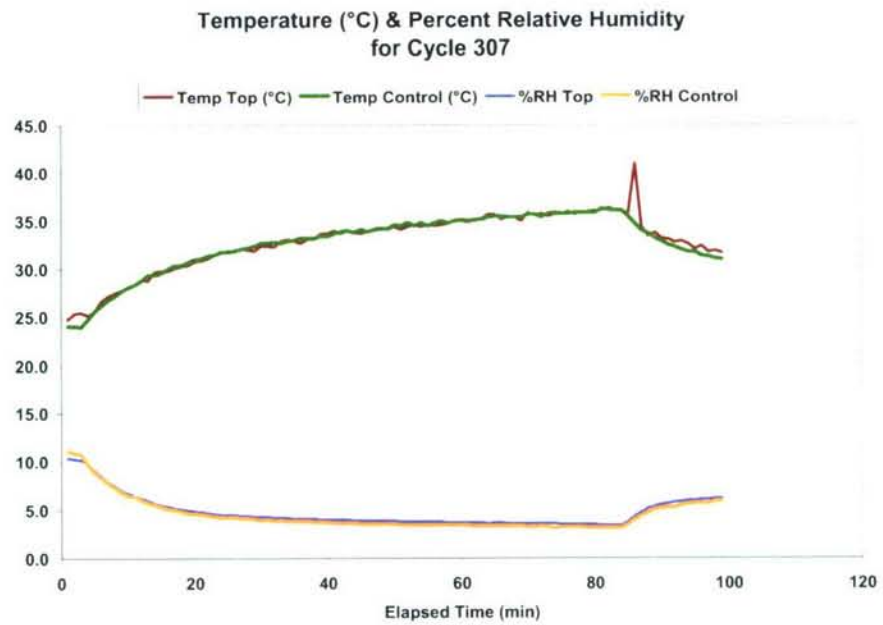

Figure C.4.2 Relative Humidity and Temperature Control Chart Cycle 307

C.5 Control Chart for Cycle 308

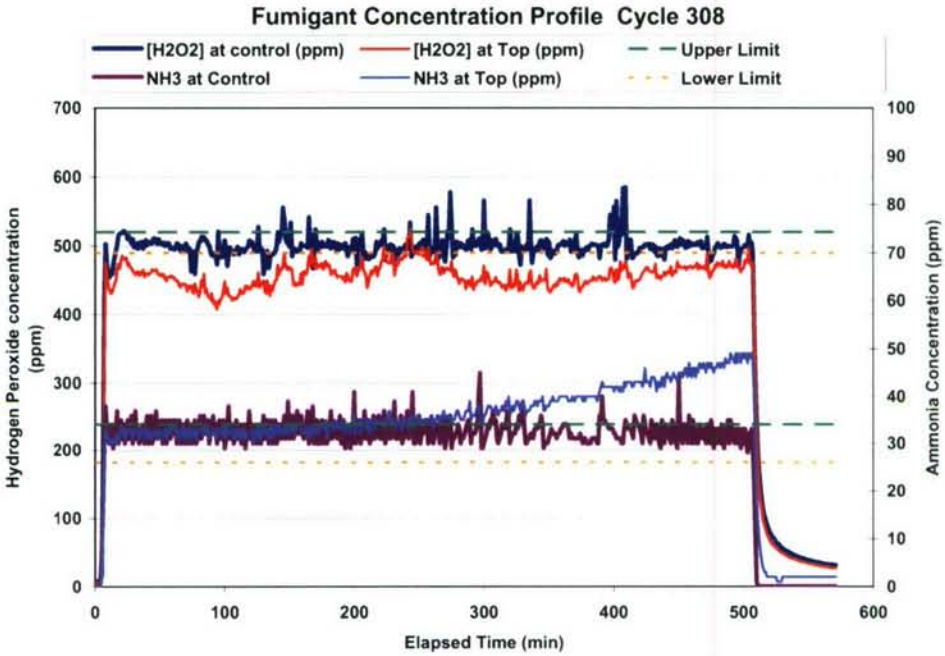

Figure C.5.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 308

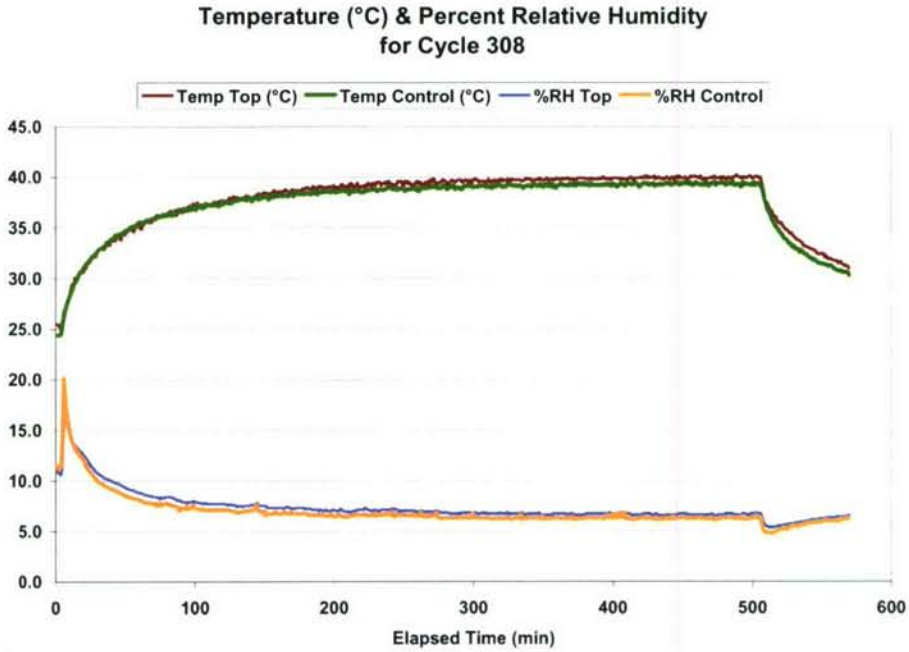

Figure C.5.2 Relative Humidity and Temperature Control Chart Cycle 308

C.6 Control Chart for Cycle 310

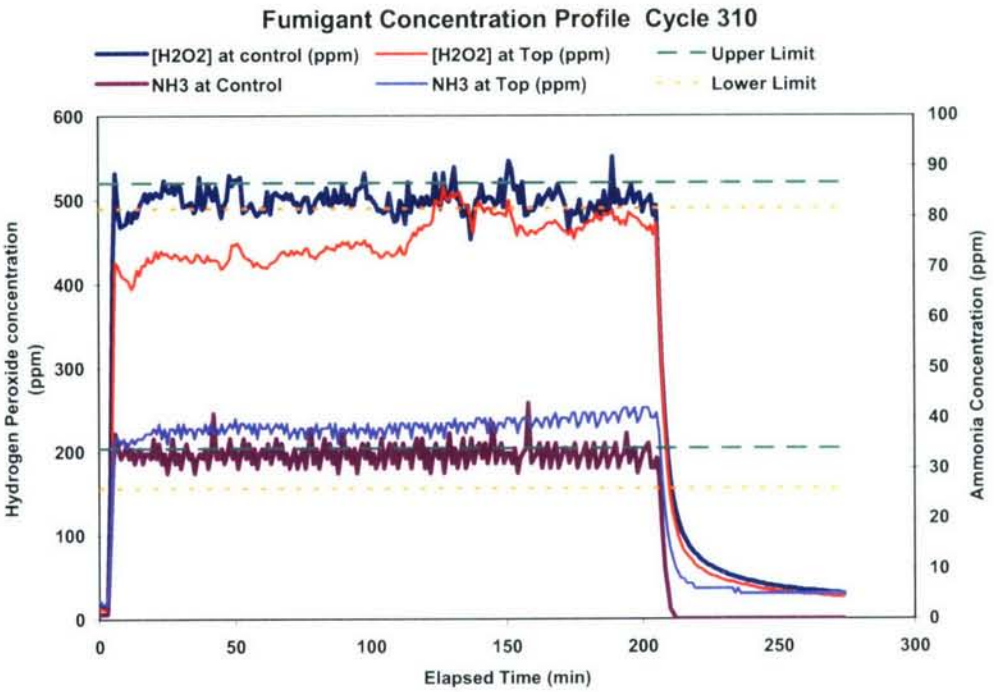

Figure C.6.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 310

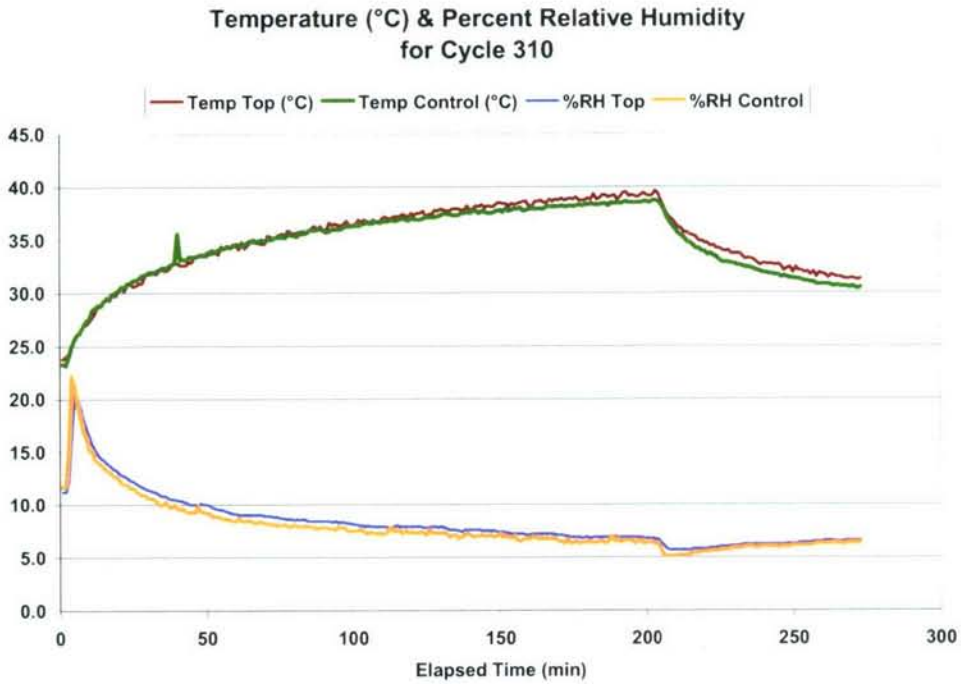

Figure C.6.2 Relative Humidity and Temperature Control Chart Cycle 310

C.7 Control Chart for Cycle 311

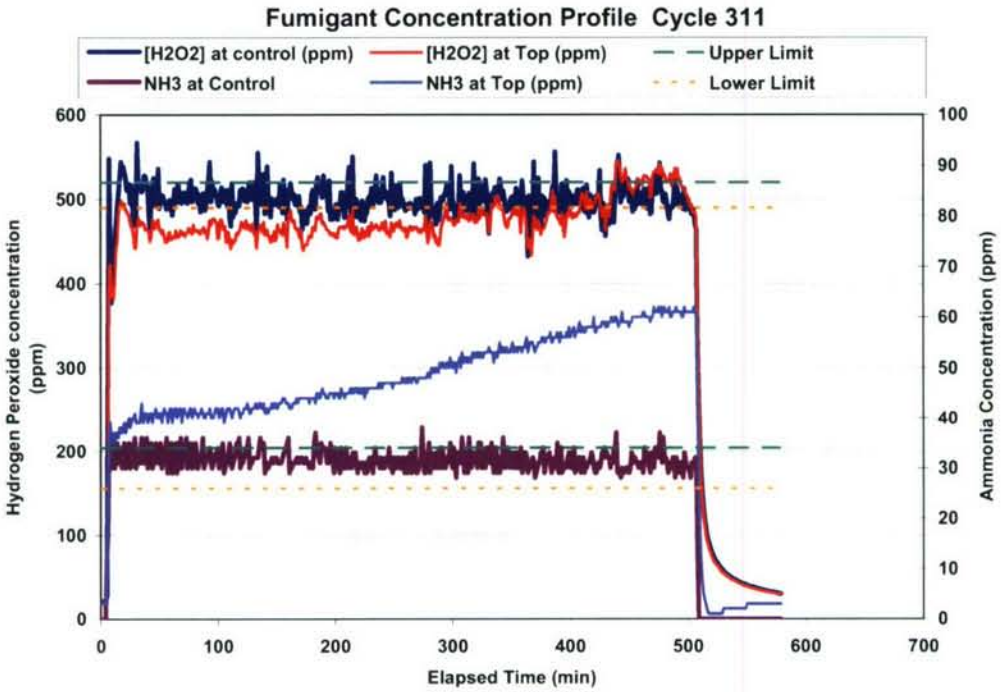

Figure C.7.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 311

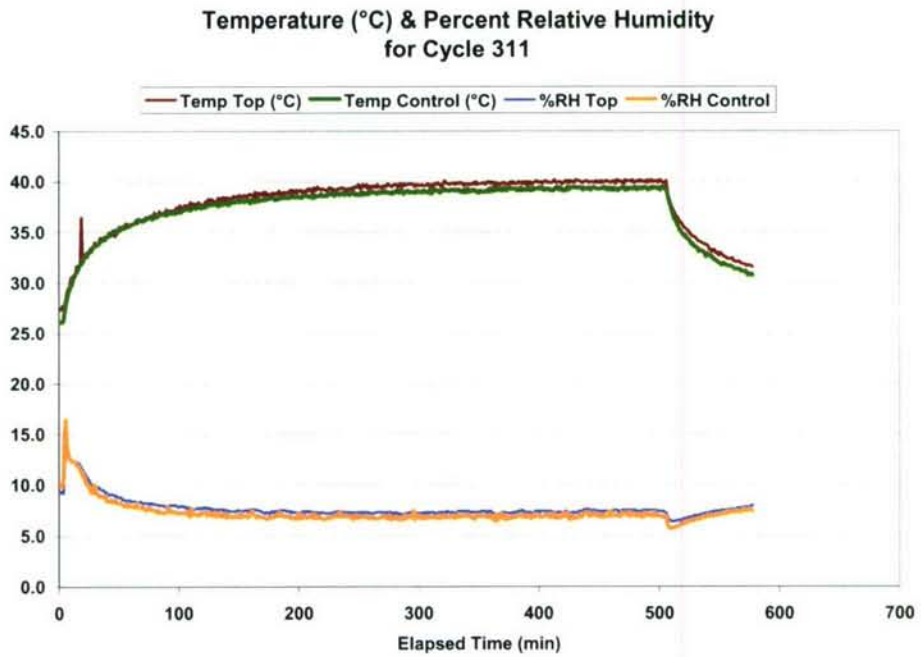

Figure C.7.2 Relative Humidity and Temperature Control Chart Cycle 311

C.8 Control Chart for Cycle 315

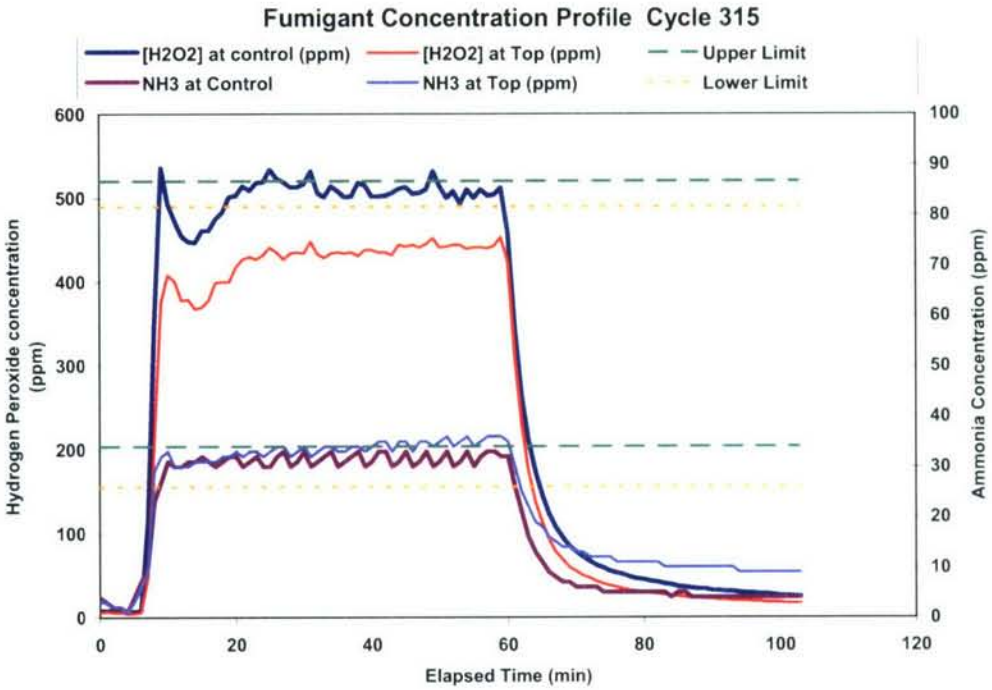

Figure C.8.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 315

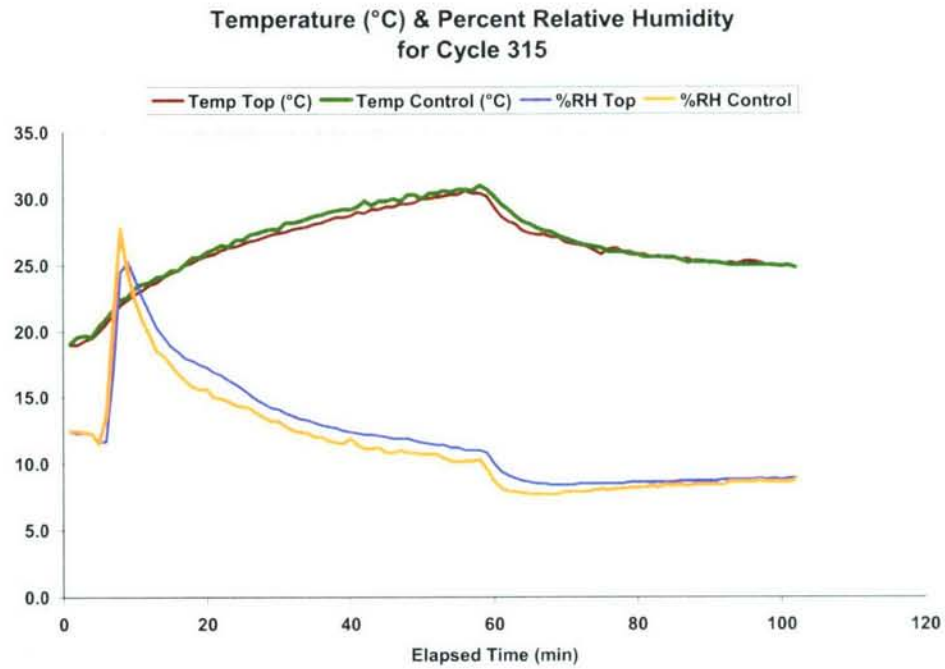

Figure C.8.2 Relative Humidity and Temperature Control Chart Cycle 315

C.9 Control Chart for Cycle 317

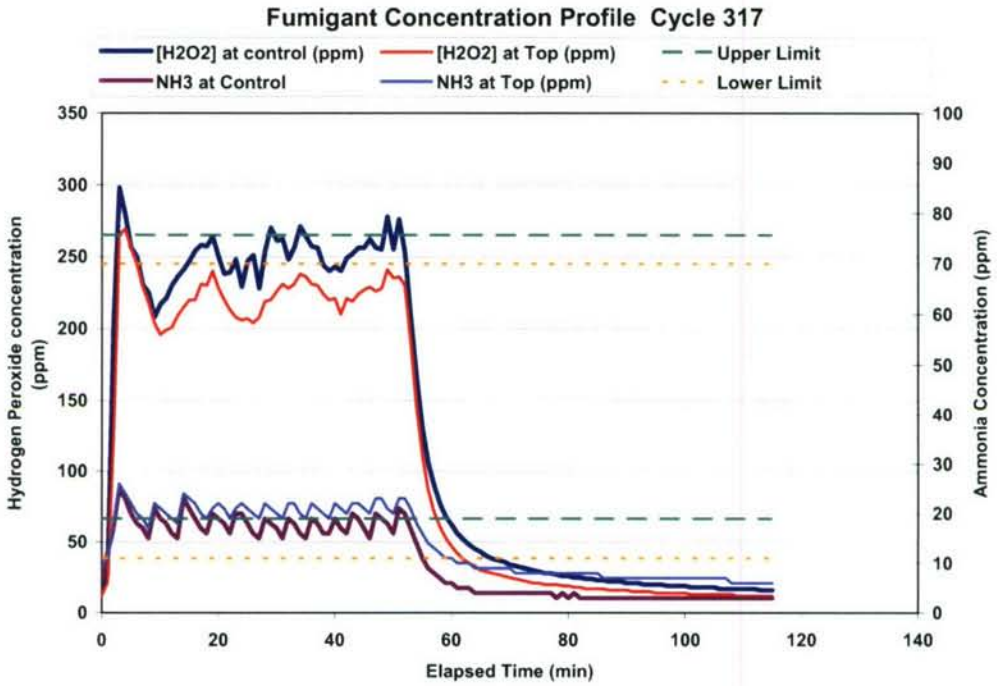

Figure C.9.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 317

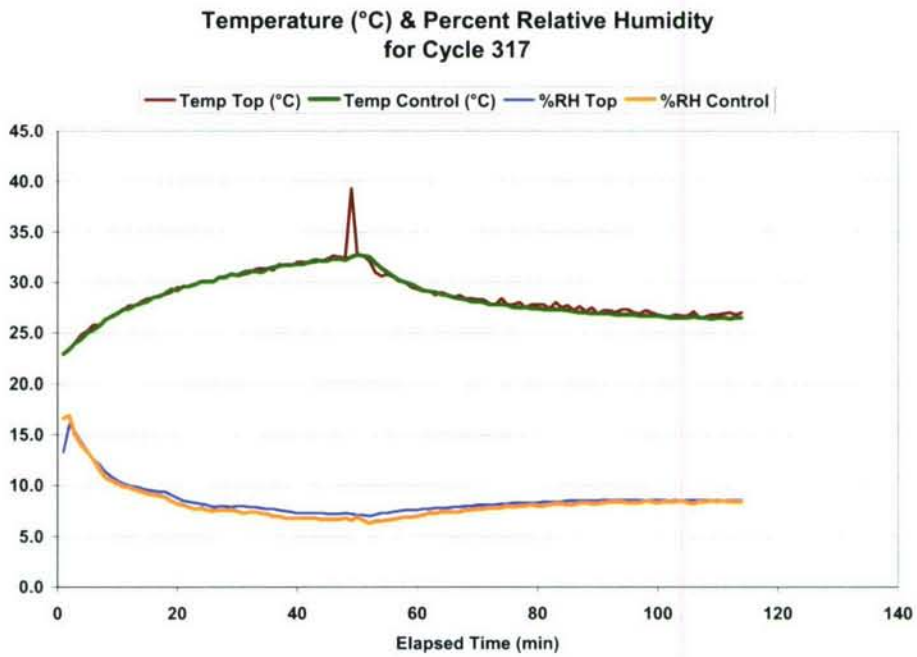

Figure C.9.2 Relative Humidity and Temperature Control Chart Cycle 317

C.10 Control Chart for Cycle 318

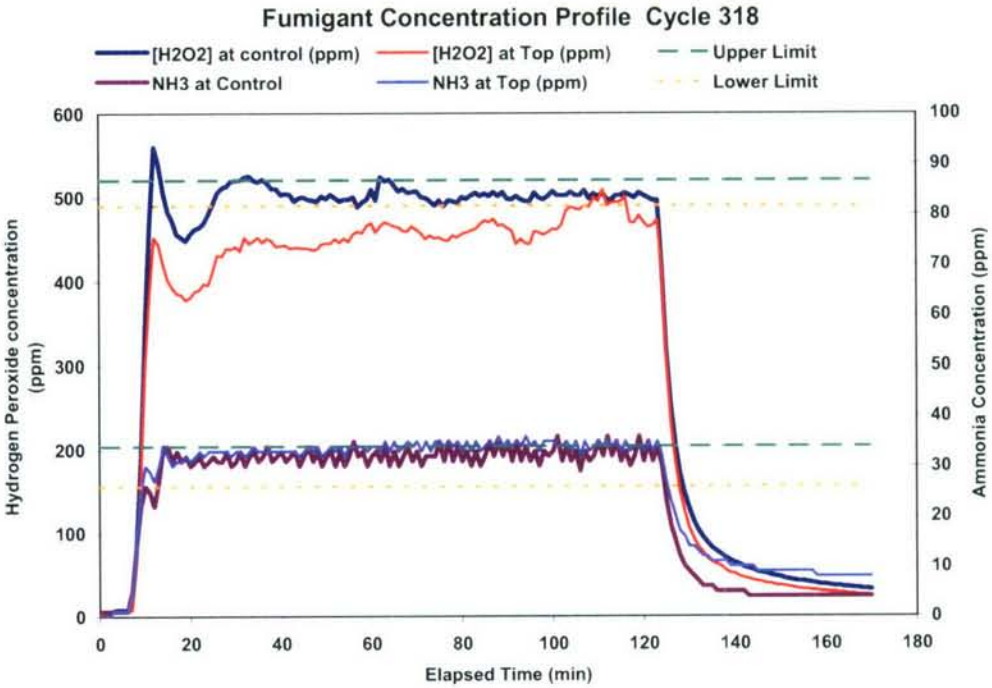

Figure C.10.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 318

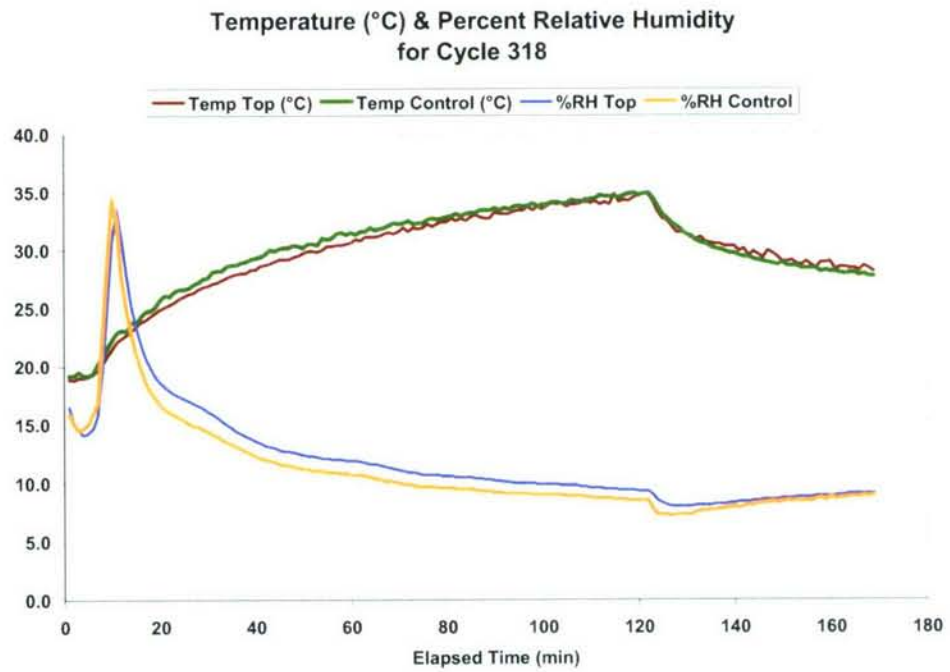

Figure C.10.2 Relative Humidity and Temperature Control Chart Cycle 318

C.11 Control Chart for Cycle 319

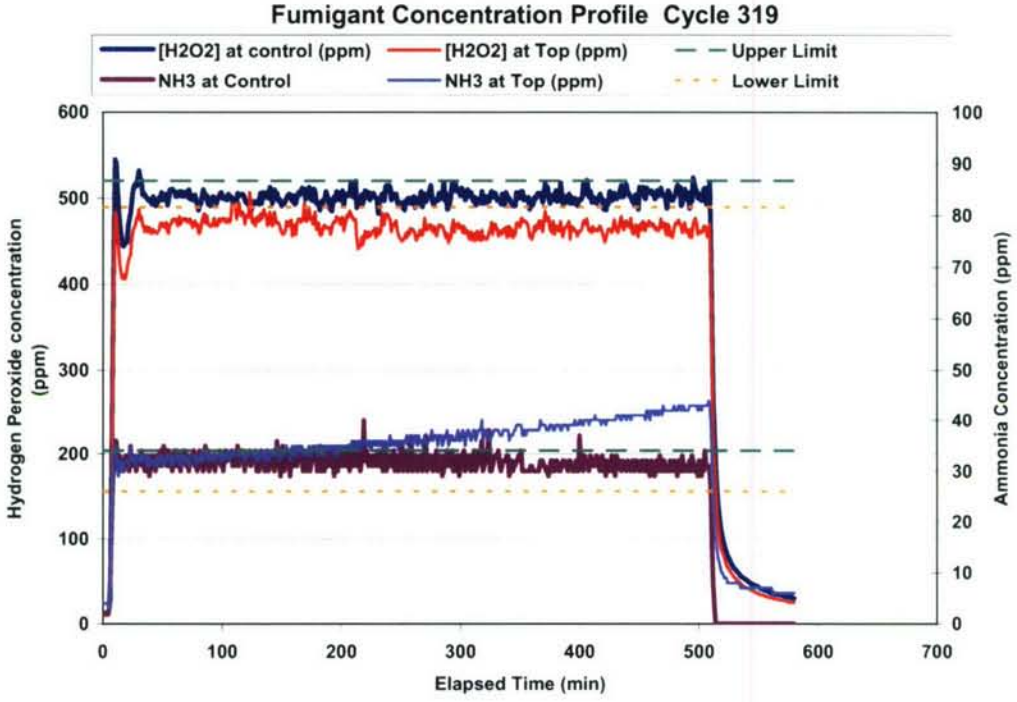

Figure C.11.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 319

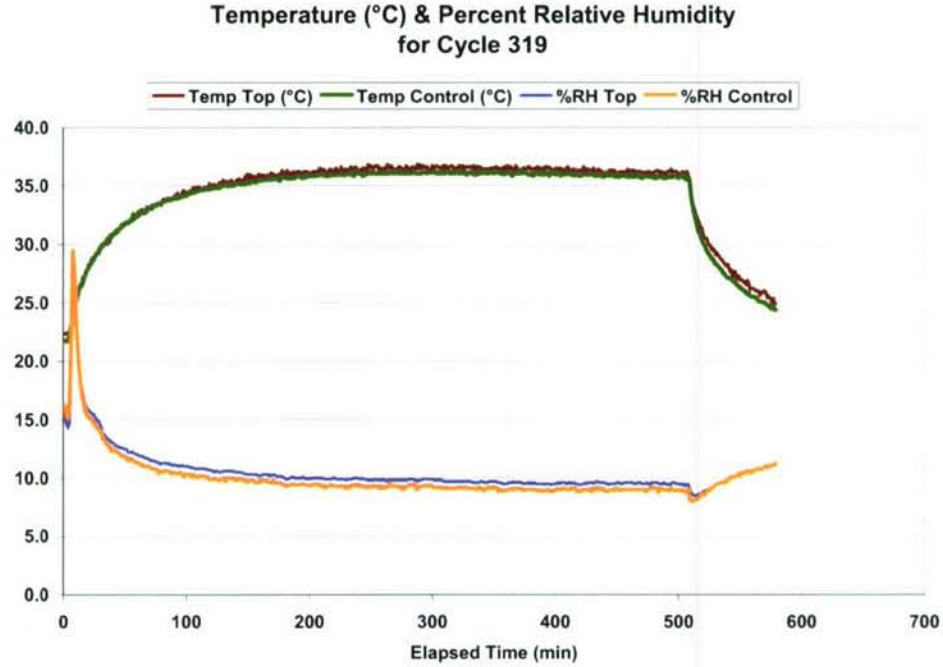

Figure C.11.2 Relative Humidity and Temperature Control Chart Cycle 319

C.12 Control Chart for Cycle 320

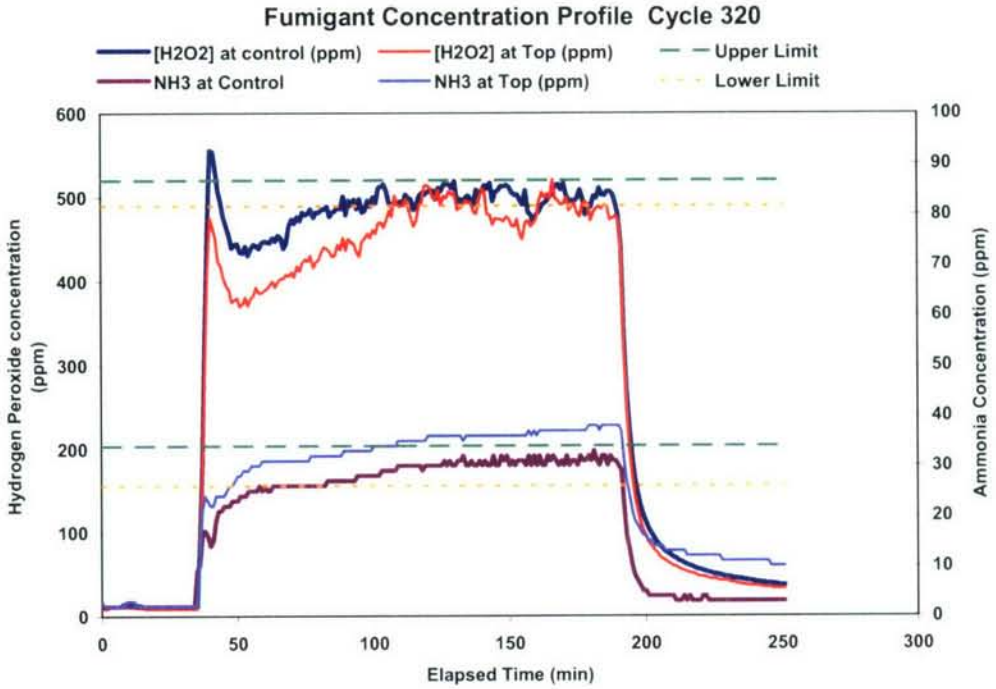

Figure C.12.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 320

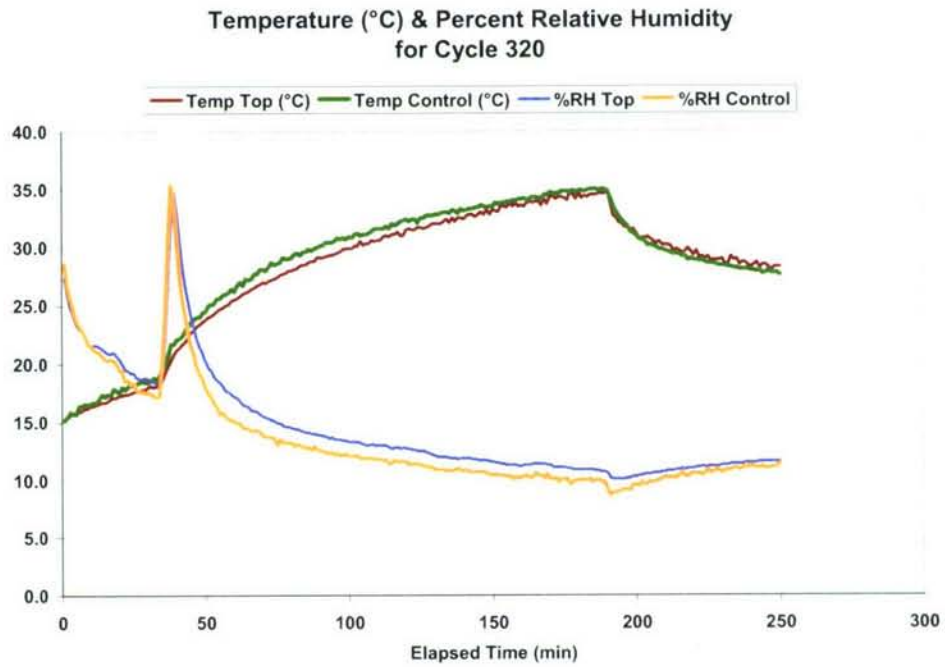

Figure C.12.2 Relative Humidity and Temperature Control Chart Cycle 320

C.13 Control Chart for Cycle 321

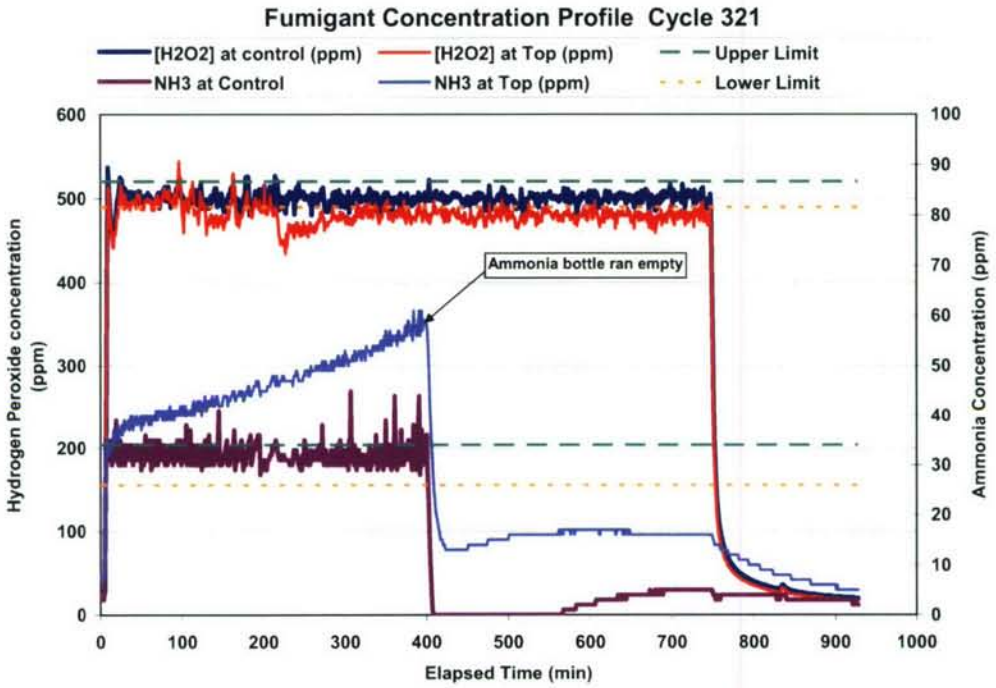

Figure C.13.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 321

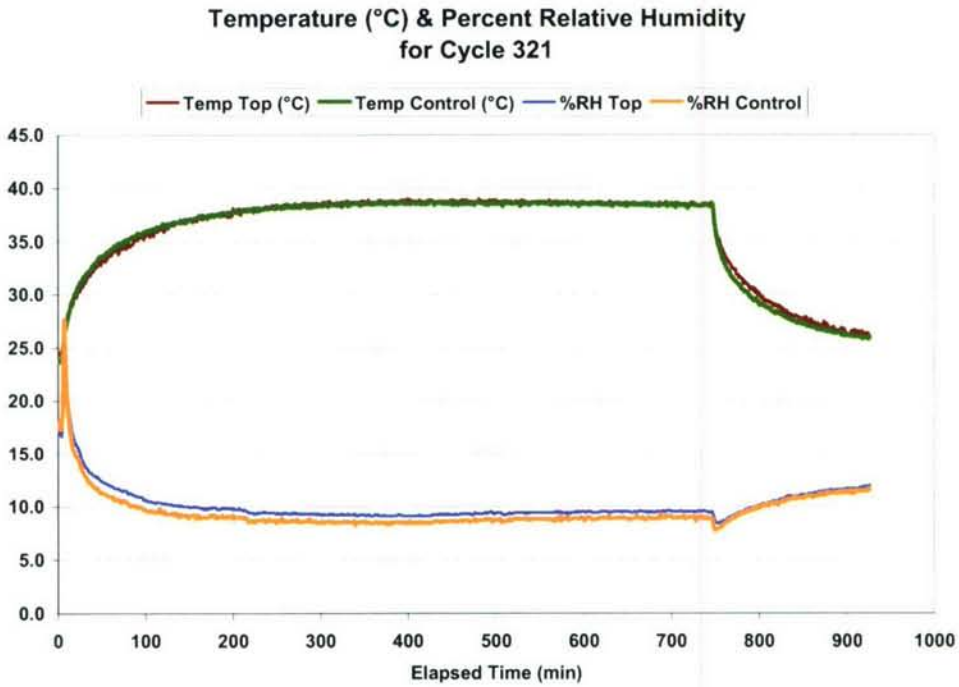

Figure C.13.2 Relative Humidity and Temperature Control Chart Cycle 321

C.14 Control Chart for Cycle 322

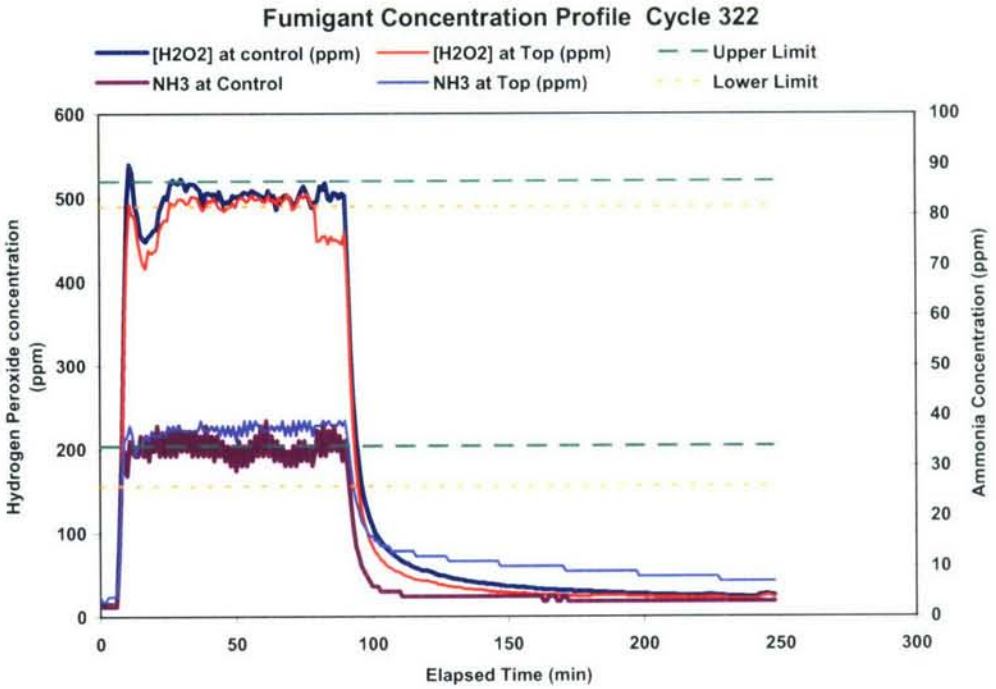

Figure C.14.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 322

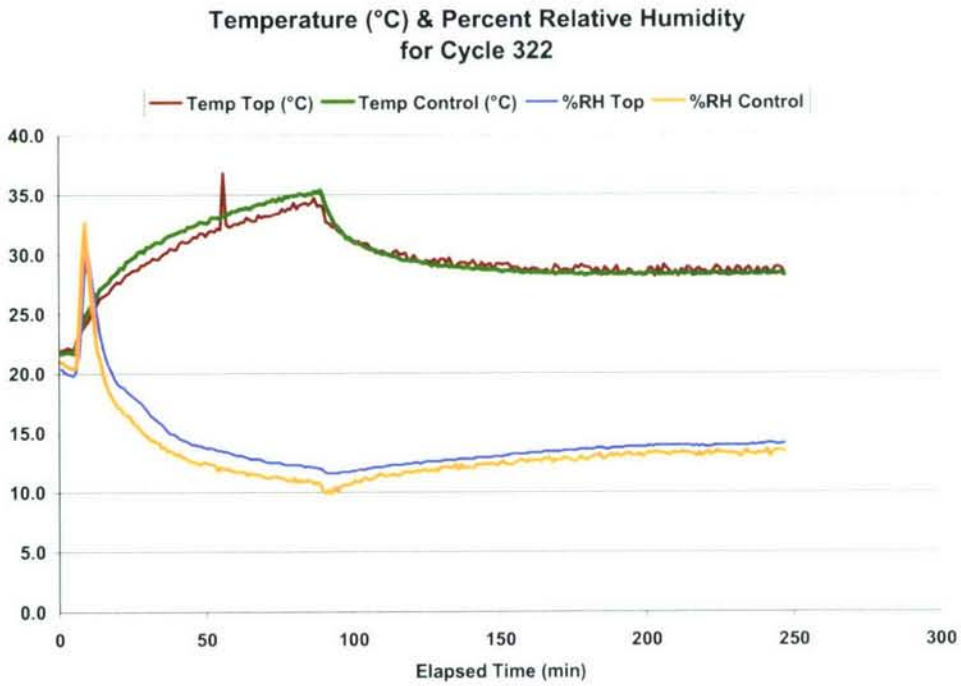

Figure C.14.2 Relative Humidity and Temperature Control Chart Cycle 322

C.15 Control Chart for Cycle 323

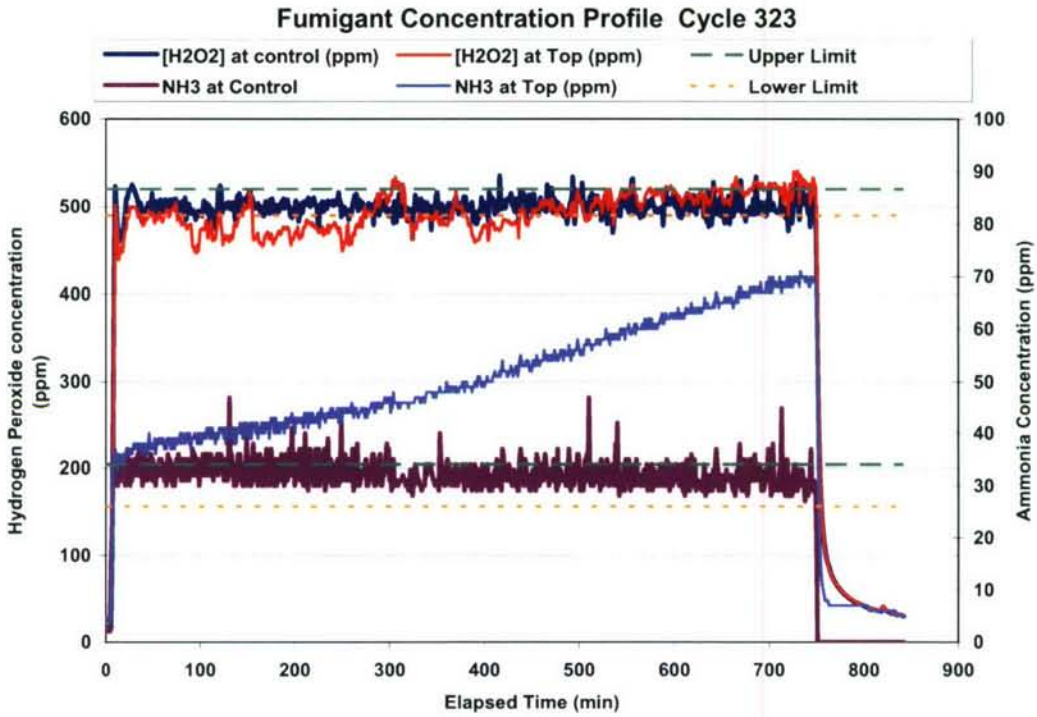

Figure C.15.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 323

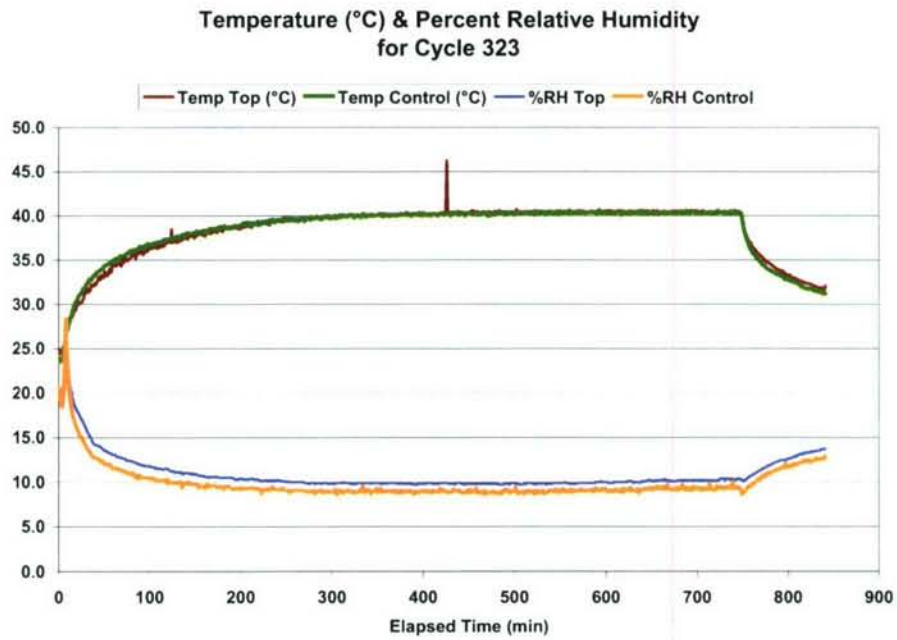

Figure C.15.2 Relative Humidity and Temperature Control Chart Cycle 323

C.16 Control Chart for Cycle 324

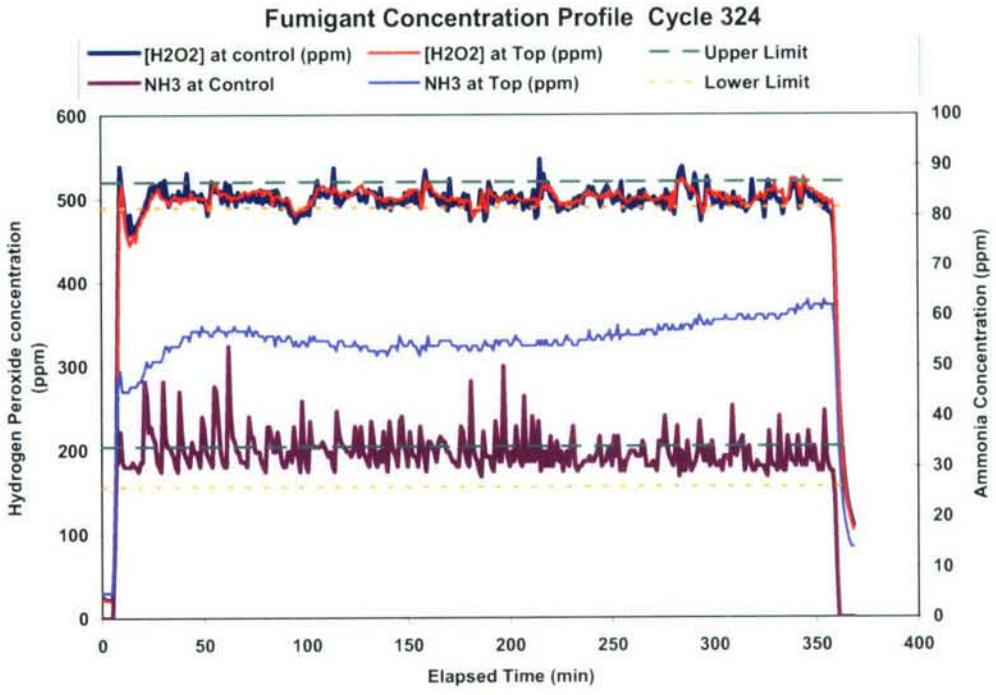

Figure C.16.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 324

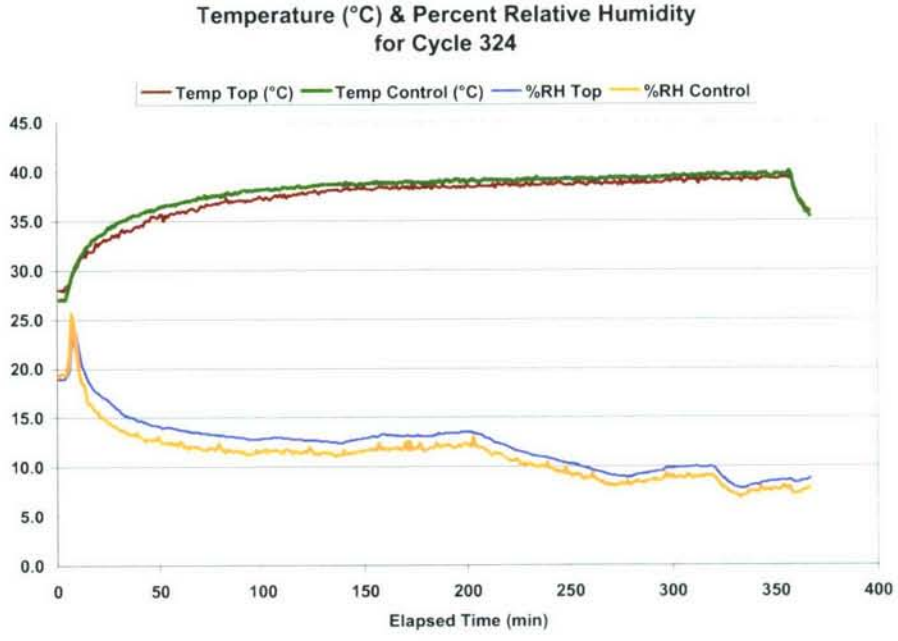

Figure C.16.2 Relative Humidity and Temperature Control Chart Cycle 324

C.17 Control Chart for Cycle 330

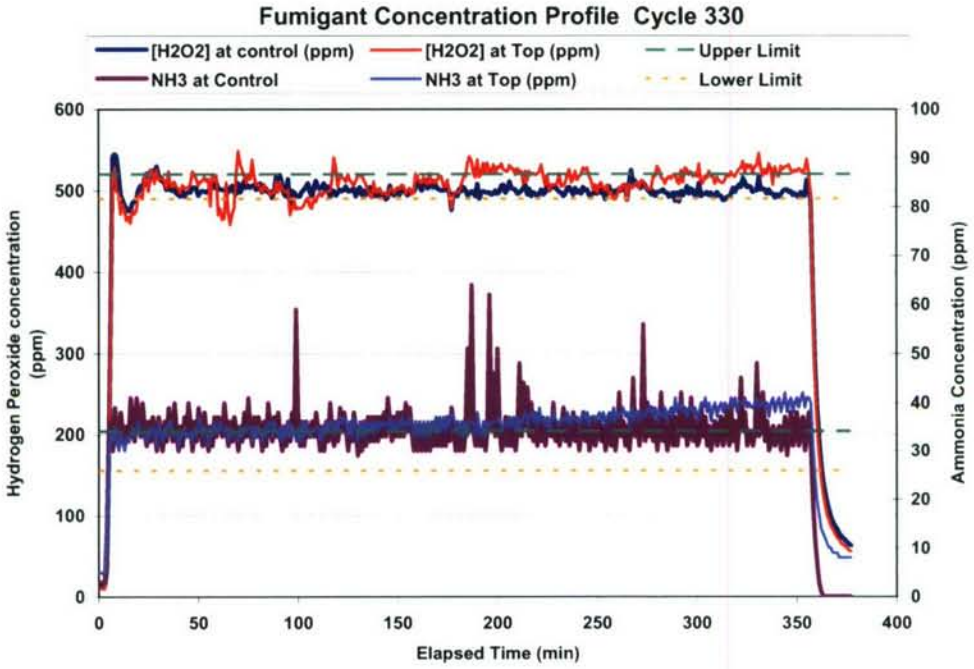

Figure C.17.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 330

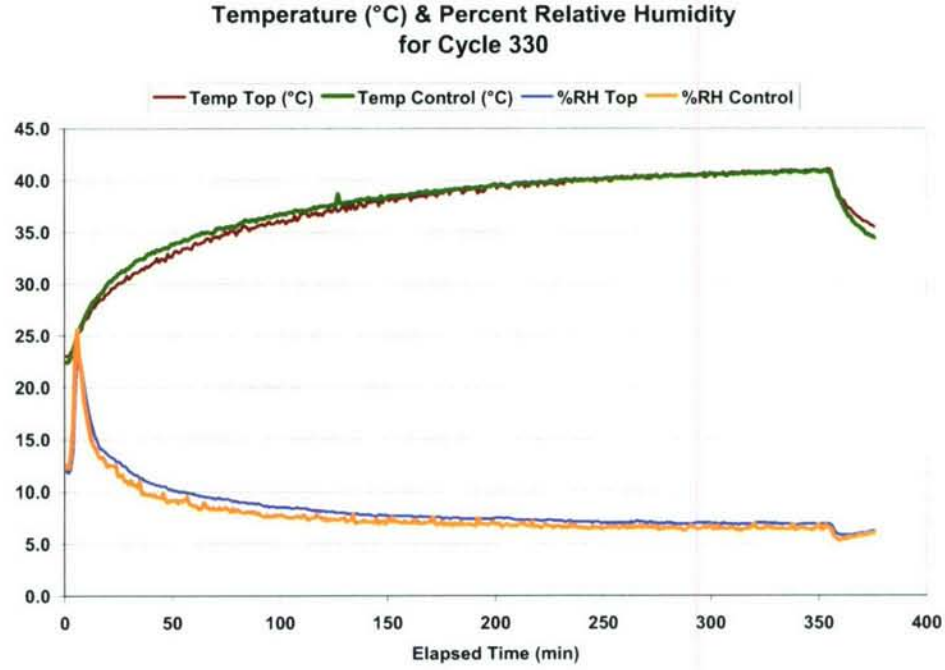

Figure C.17.2 Relative Humidity and Temperature Control Chart Cycle 330

C.18 Control Chart for Cycle 331

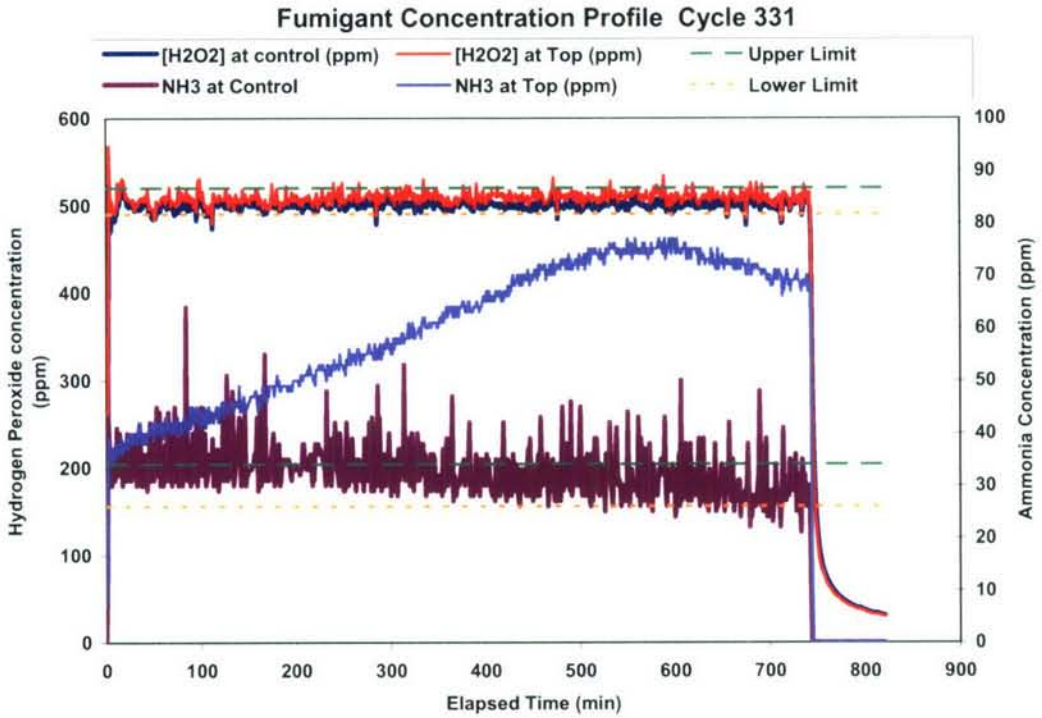

Figure C.18.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 331

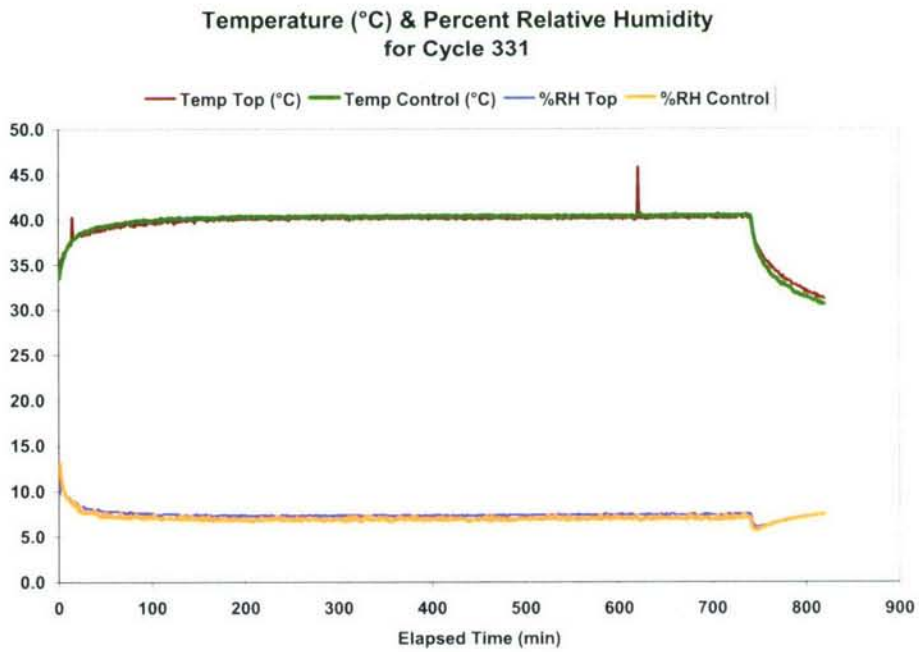

Figure C.18.2 Relative Humidity and Temperature Control Chart Cycle 331

C.19 Control Chart for Cycle 332

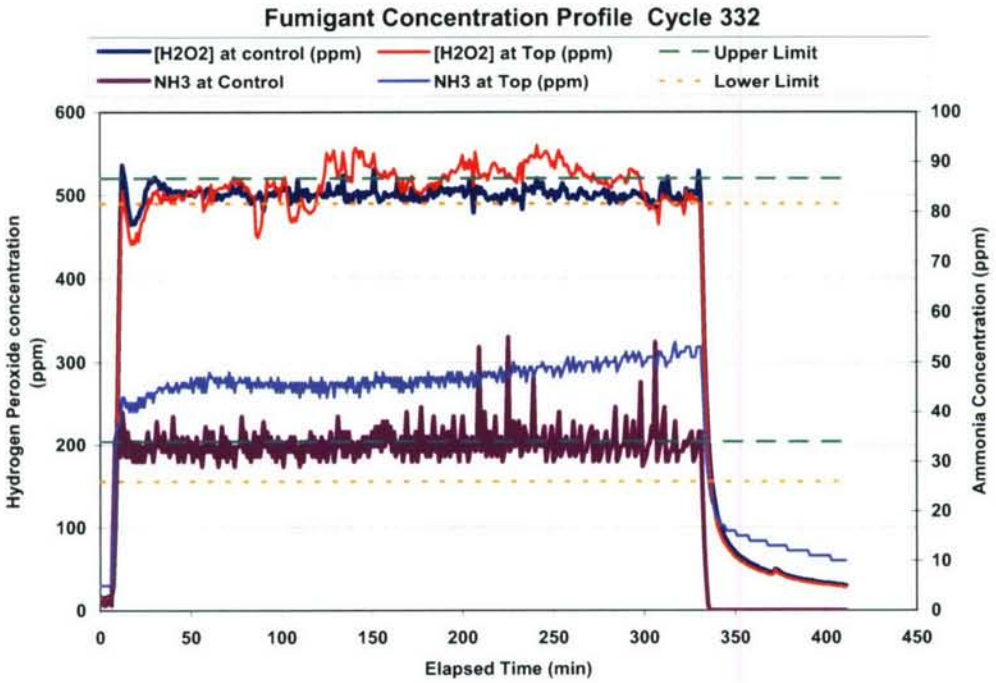

Figure C.19.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 332

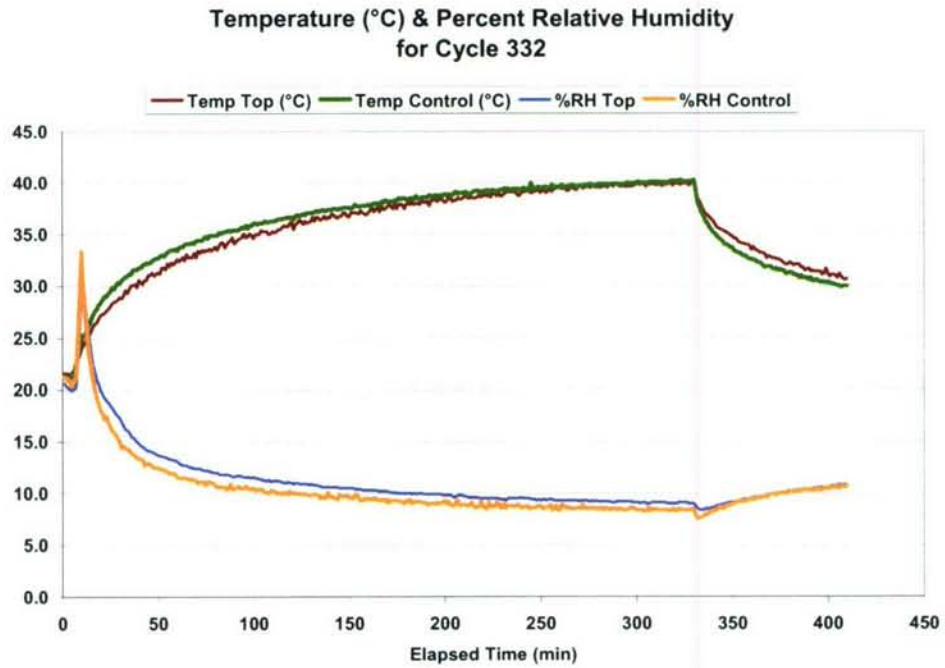

Figure C.19.2 Relative Humidity and Temperature Control Chart Cycle 332

C.20 Control Chart for Cycle 333

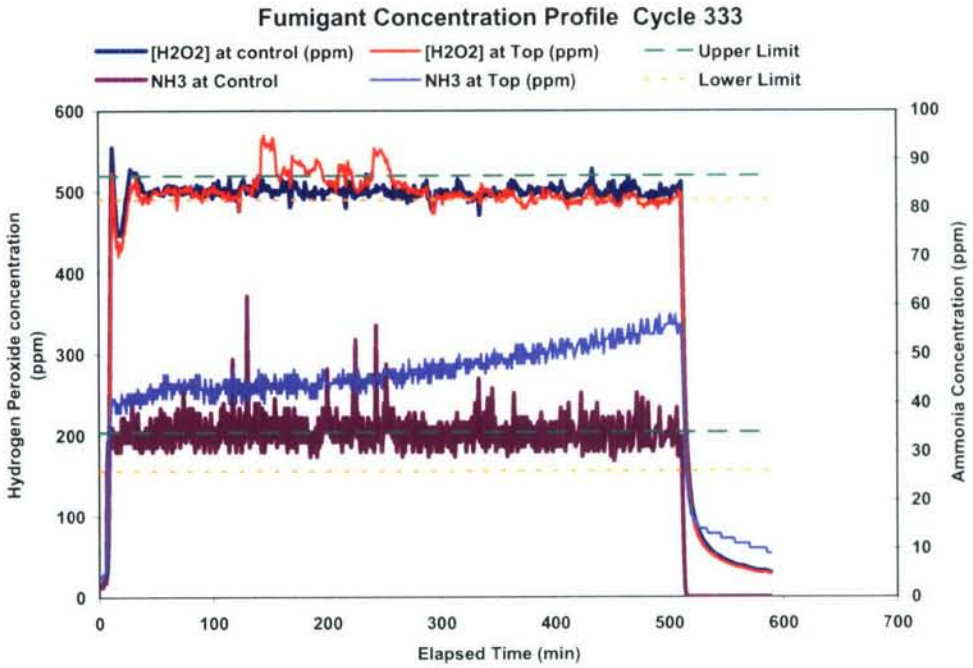

Figure C.20.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 333

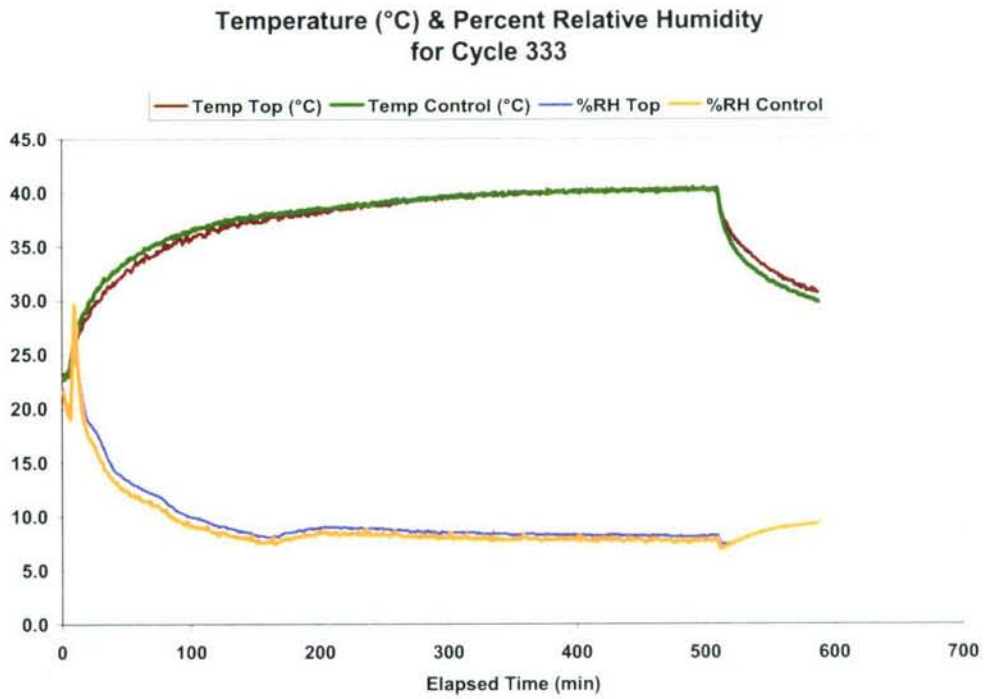

Figure C.20.2 Relative Humidity and Temperature Control Chart Cycle 333

C.21 Control Chart for Cycle 334

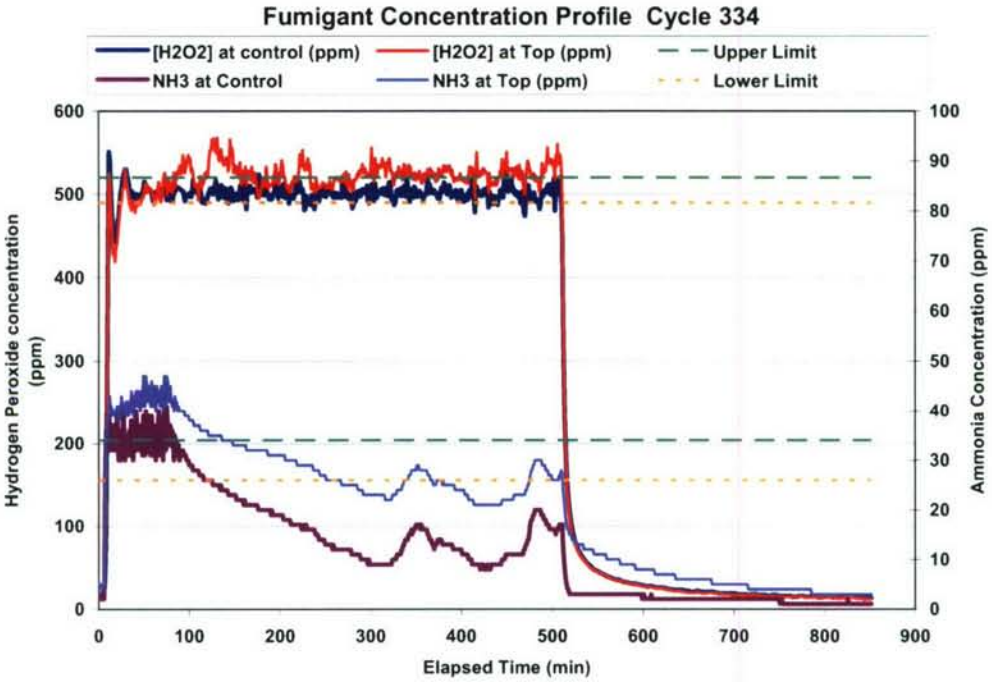

Figure C.21.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 334

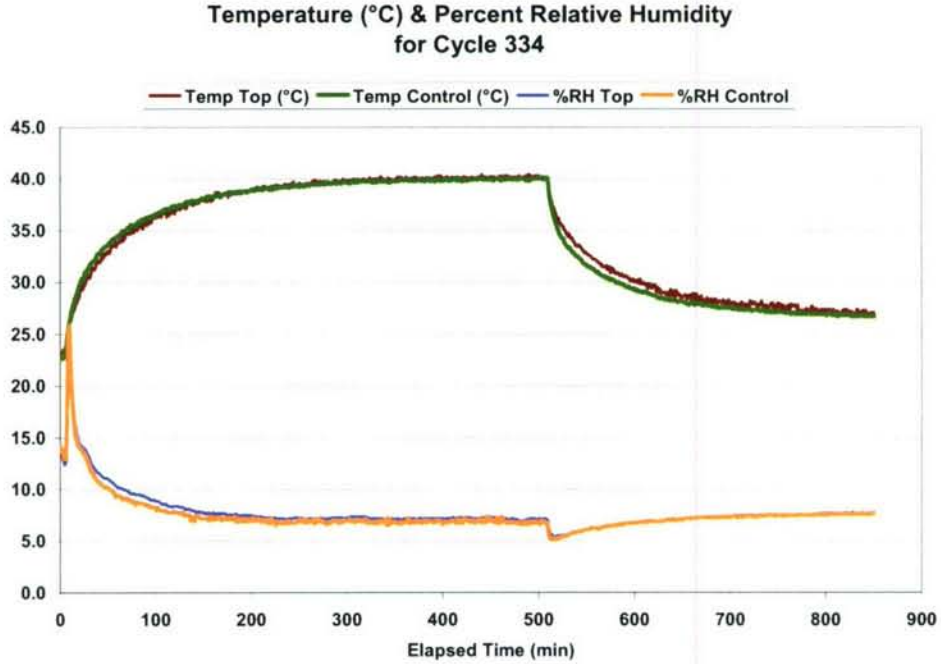

Figure C.21.2 Relative Humidity and Temperature Control Chart Cycle 334

C.22 Control Chart for Cycle 335

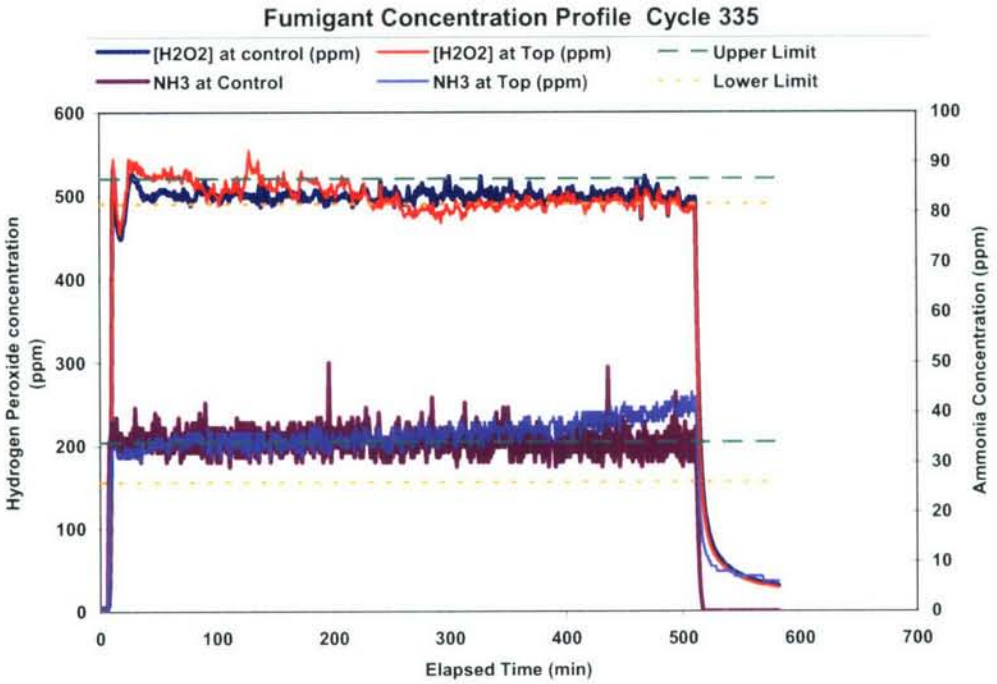

Figure C.22.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 335

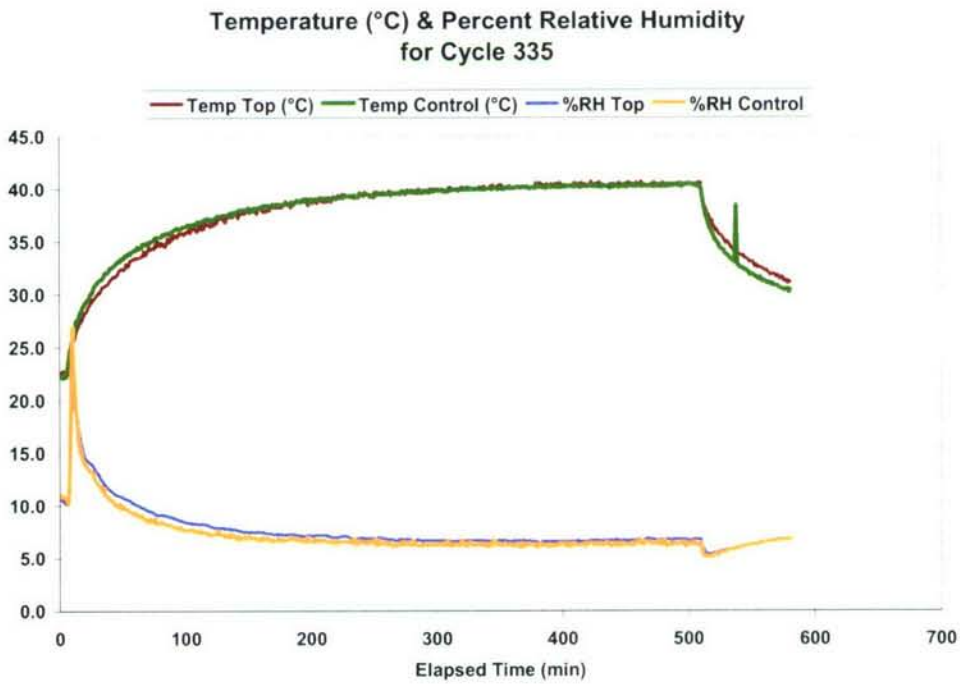

Figure C.22.2 Relative Humidity and Temperature Control Chart Cycle 335

C.23 Control Chart for Cycle 336

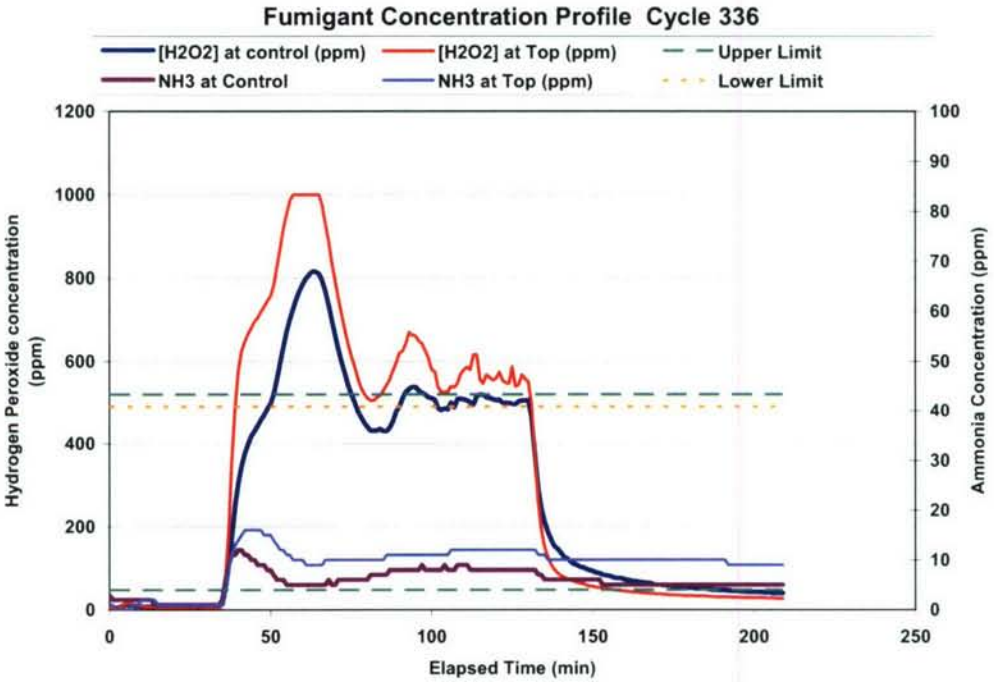

Figure C.23.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 336

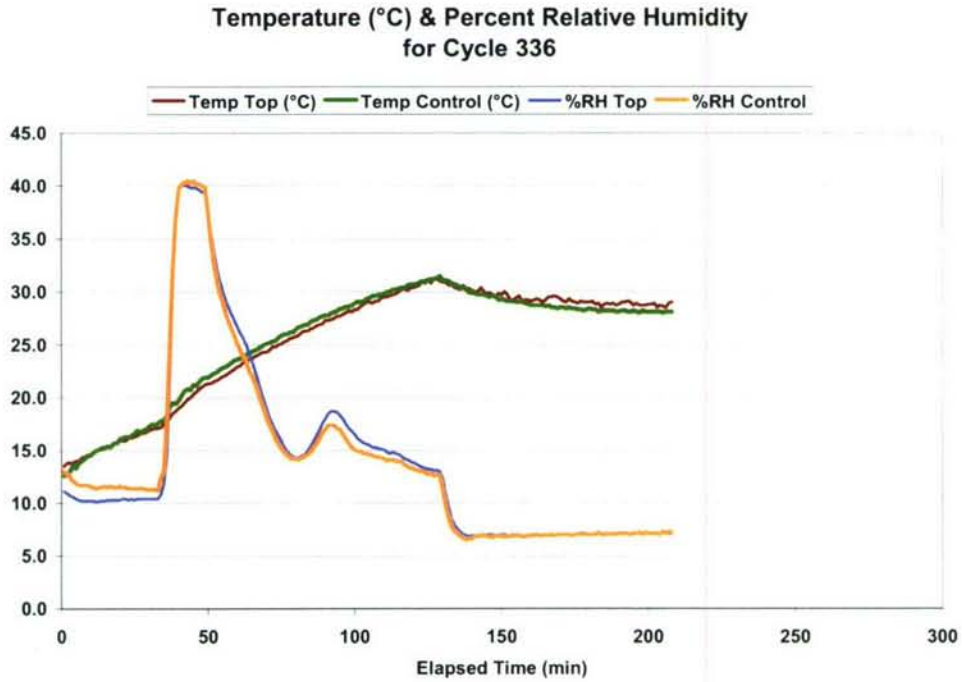

Figure C.23.2 Relative Humidity and Temperature Control Chart Cycle 336

C.24 Control Chart for Cycle 337

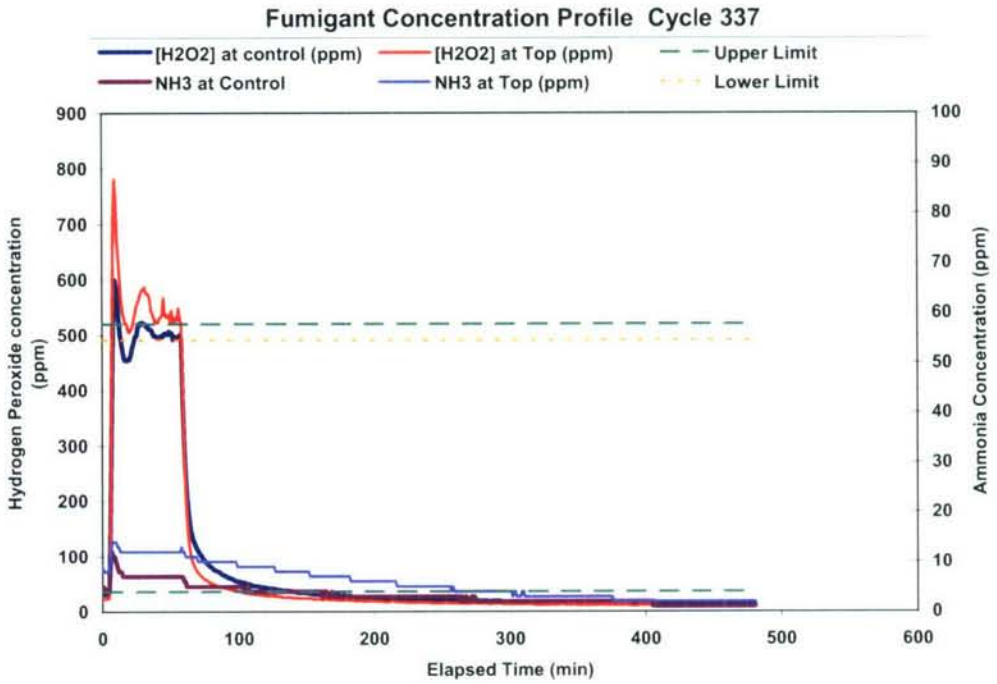

Figure C.24.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 337

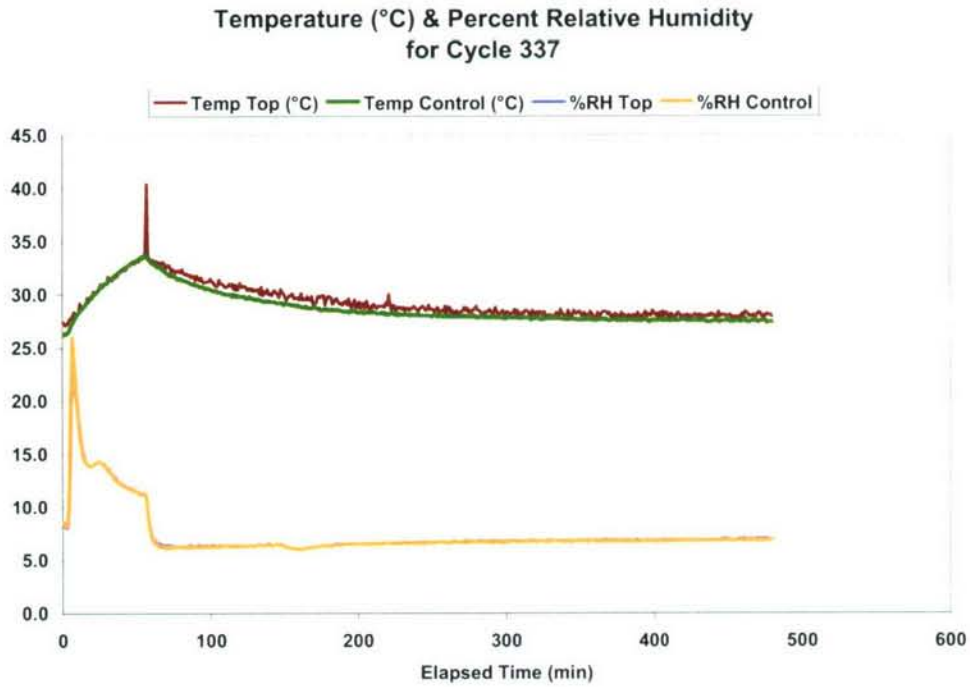

Figure C.24.2 Relative Humidity and Temperature Control Chart Cycle 337

C.25 Control Chart for Cycle 339

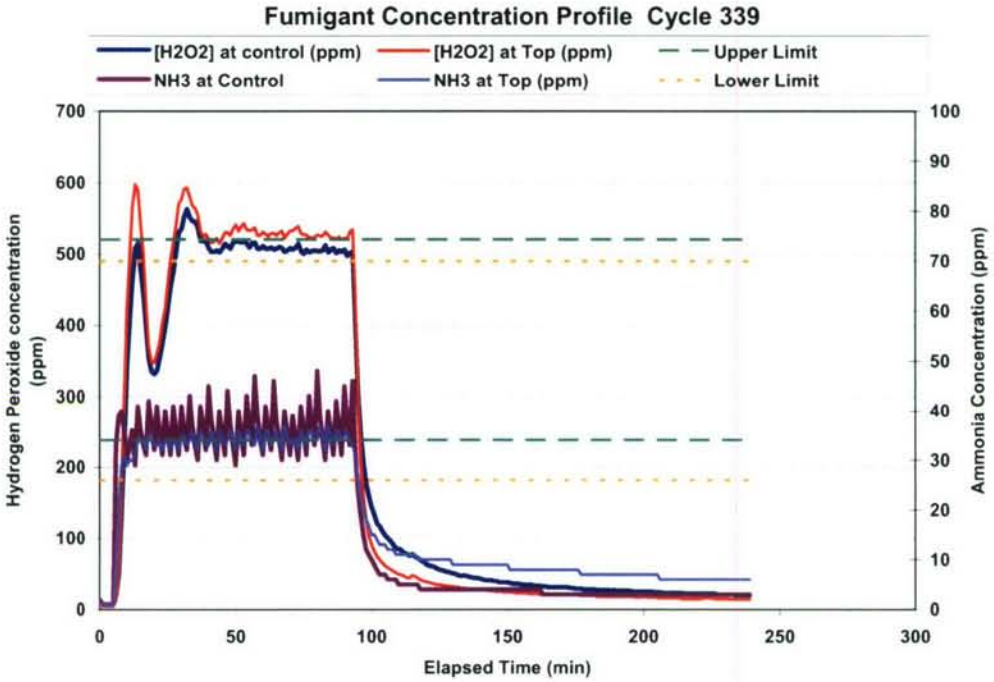

Figure C.25.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 339

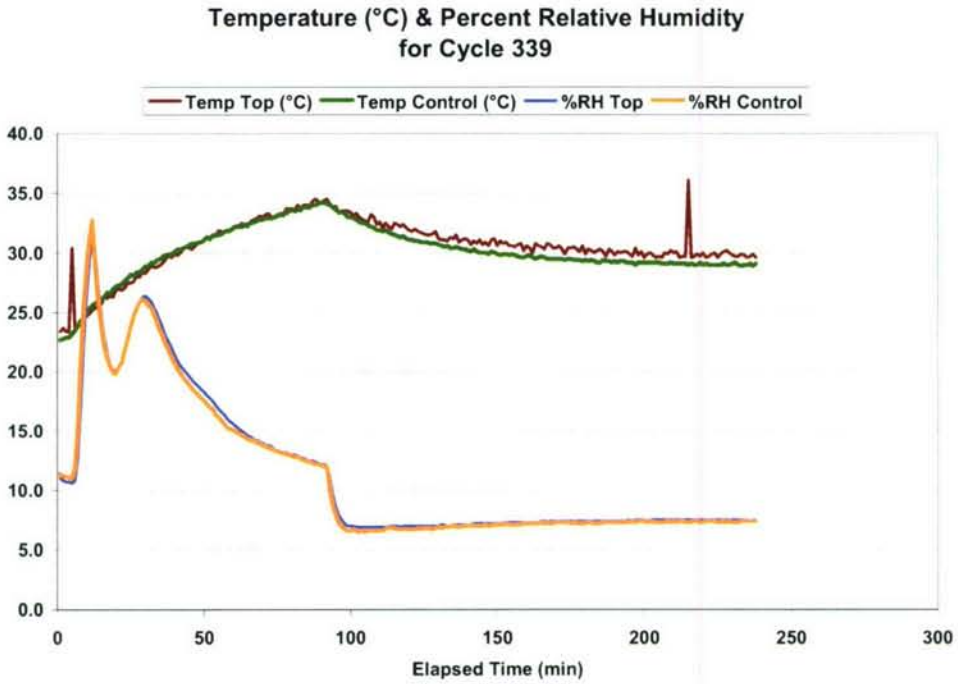

Figure C.25.2 Relative Humidity and Temperature Control Chart Cycle 339

C.26 Control Chart for Cycle 243

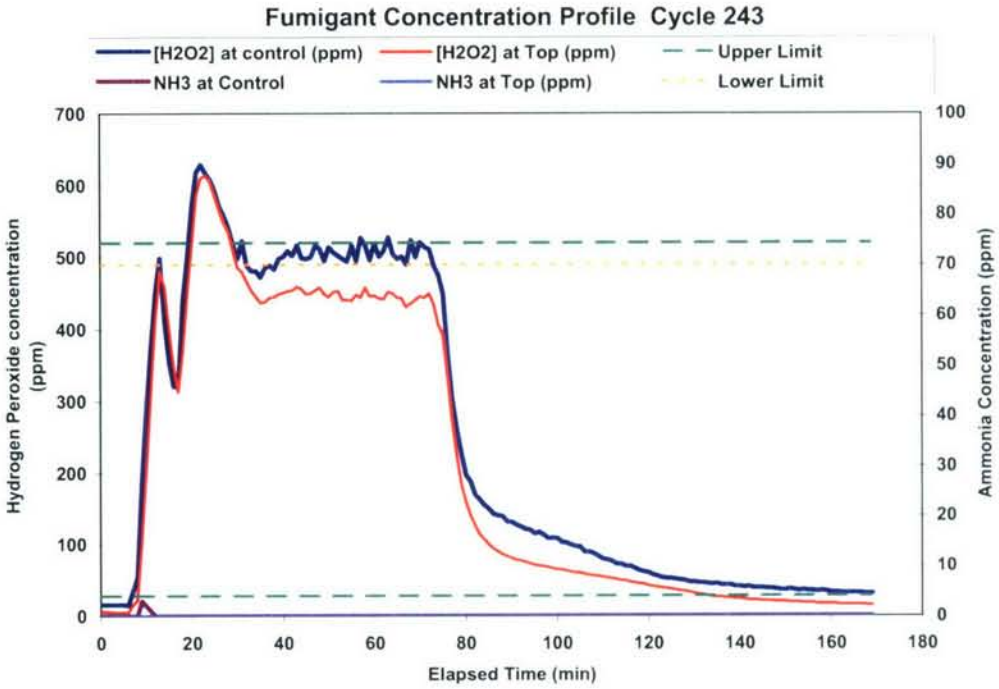

Figure C.26.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 243

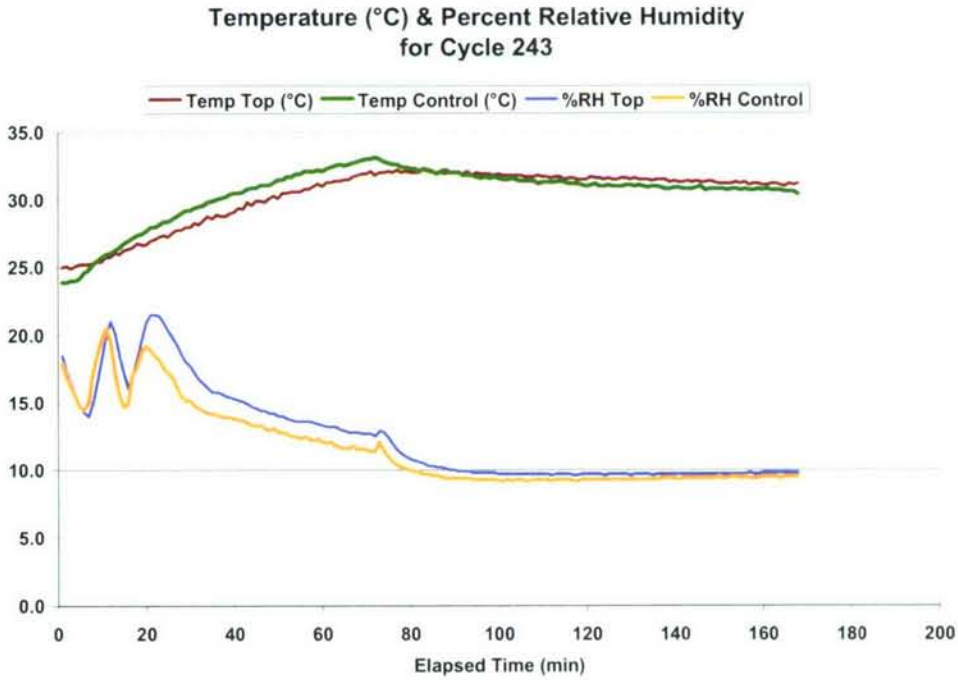

Figure C.26.2 Relative Humidity and Temperature Control Chart Cycle 243

C.27 Control Chart for Cycle 244

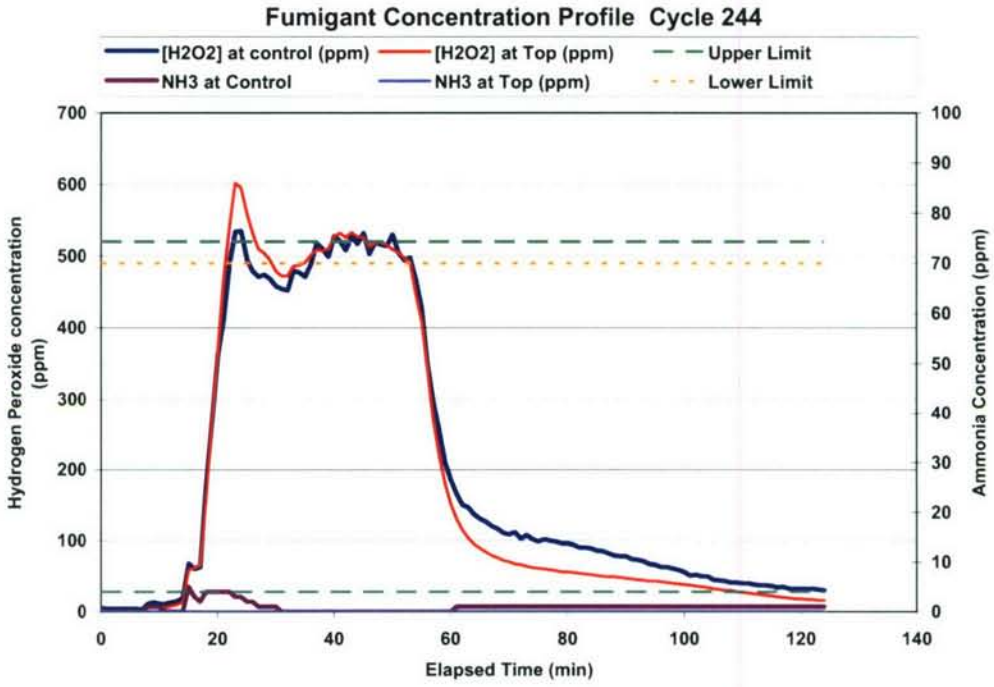

Figure C.27.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 244

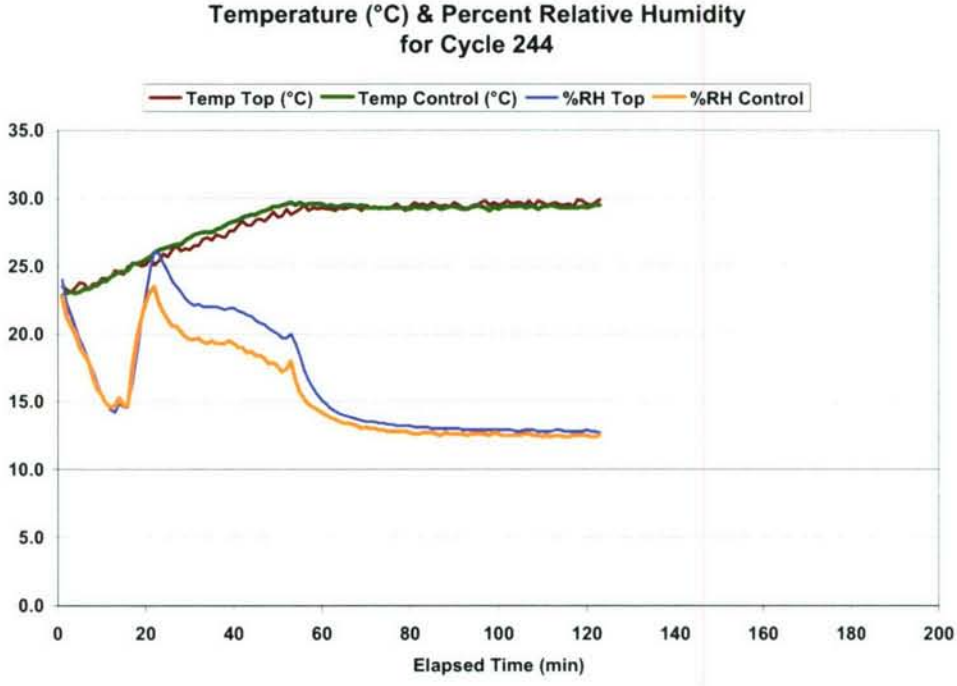

Figure C.27.2 Relative Humidity and Temperature Control Chart Cycle 244

C.28 Control Chart for Cycle 245

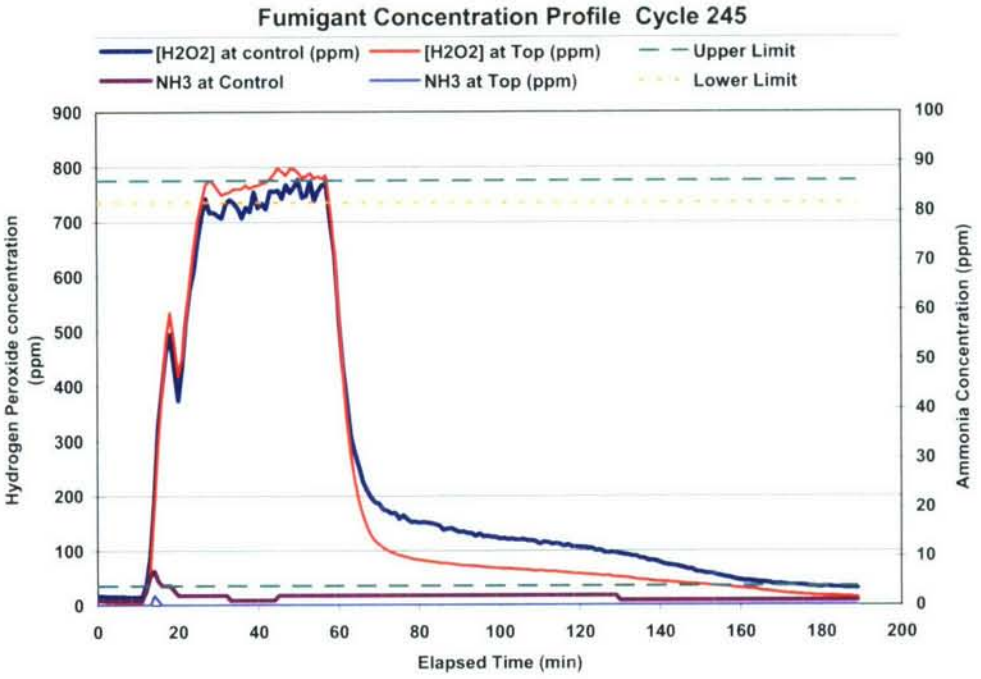

Figure C.28.1 Hydrogen Peroxide and Ammonia Control Chart Cycle 245

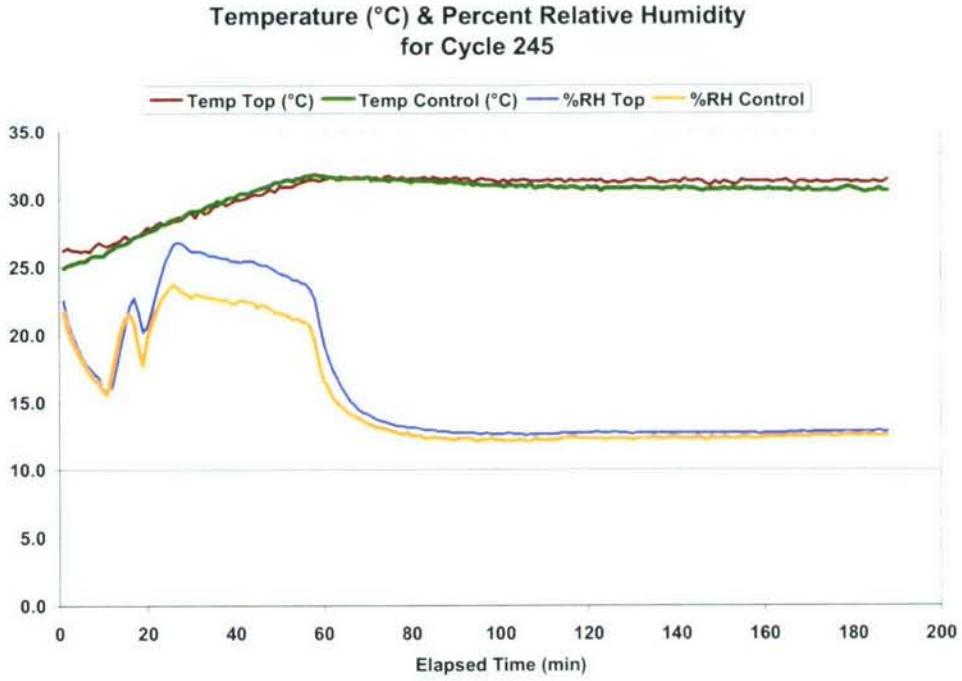

Figure C.28.2 Relative Humidity and Temperature Control Chart Cycle 245